

| Validated End-User | Eligible Items (By ECCN) | Eligible Destination |
|--|--|--|
| Semiconductor Manufacturing International Corporation. | 1C350.c.3; 1C350.d.7; 2B006.b.1; 2B230; 2B350.d.2; 2B350.g.3; 2B350.i.4; 3B001.a; 3B001.b; 3B001.c; 3B001.d; 3B001.e; 3B001.f; 3C001; 3C002; 3C004; 5B002; 5E002 (limited to "technology" according to the General Technology Note for the "production" of integrated circuits controlled by ECCN 5A002 that has been successfully reviewed under the encryption review process specified in §§ 740.17.b.2 or 740.17.b.3 and 742.15 of the EAR). | National Semiconductor Hong Kong Limited, Shenzhen Representative Office, Room 1709 Di Wang Commercial Centre, Shung Hing Square, 5002 Shenna Road East, Shenzhen, China 518008. Semiconductor Manufacturing International (Shanghai) Corporation, 18 Zhang Jiang Rd., Pudong New Area, Shanghai, China 201203. Semiconductor Manufacturing International (Tianjin) Corporation, 19 Xing Hua Avenue, Xi Qing Economic Development Area, Tianjin, China 300385. Semiconductor Manufacturing International (Beijing) Corporation, No. 18 Wen Chang Road, Beijing Economic-Technological Development Area, Beijing, China 100176. Semiconductor Manufacturing International (Chengdu) Corporation, Assembly and Testing (AT2) Facility, 8-8 Kexin Road, Export Processing Zone (West Area), Chengdu, China 611731. Cension Semiconductor Manufacturing Corporation, 3/F, 8-1 Kexin Road, Export Processing Zone (West Area), Chengdu, China 611731. Headquarters and Fab. 1 of HHNEC, No. 1188 Chuan Qiao Rd., Pu Dong, Shanghai, China 201206. Fab. 2 of HHNEC, No. 668 Guo Shou Jing Rd., Zhang Jiang High Tech Park, Pu Dong, Shanghai, China 201203. |
| Shanghai Hua Hong NEC Electronics Company, Ltd. | 1C350.c.3; 1C350.d.7; 2B230; 2B350.d.2 2B350.g.3 2B350.i.4; 3B001.c.2; 3C002; 3C004. | Headquarters and Fab. 1 of HHNEC, No. 1188 Chuan Qiao Rd., Pu Dong, Shanghai, China 201206. Fab. 2 of HHNEC, No. 668 Guo Shou Jing Rd., Zhang Jiang High Tech Park, Pu Dong, Shanghai, China 201203. |

Dated: October 16, 2007.

Christopher A. Padilla,

Assistant Secretary for Export Administration.

[FR Doc. E7-20642 Filed 10-18-07; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Chapter I

[CBP Dec. 07-82]

Technical Corrections Regarding the Organizational Structure of U.S. Customs and Border Protection

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This document amends the U.S. Customs and Border Protection (CBP) regulations to reflect changes in the organizational structure of CBP resulting from the establishment of the new Office of International Trade, as well as the nomenclature changes effected by the transfer in 2003 of CBP to the Department of Homeland Security

and the subsequent renaming of the U.S. Customs Service as CBP.

DATES: October 19, 2007.

FOR FURTHER INFORMATION CONTACT:

Jacinto P. Juarez, Jr., Regulations and Rulings, Office of International Trade, (202) 572-8752, or Michelle Garcia, Regulations and Rulings, Office of International Trade, (202) 572-8745.

SUPPLEMENTARY INFORMATION:

Background

On November 25, 2002, the President signed the Homeland Security Act of 2002, 6 U.S.C. 101 *et seq.*, Public Law 107-296, (the "HSA"), establishing the Department of Homeland Security ("DHS"). Pursuant to section 403(1) of the HSA (6 U.S.C. 203(1)), the United States Customs Service was transferred from the Department of the Treasury to DHS effective March 1, 2003. Under section 1502 of the HSA, the Customs Service was renamed as the "Bureau of Customs and Border Protection". Subsequently, on April 23, 2007, a notice was published in the **Federal Register** (72 FR 20131) informing the public that DHS had changed the name of the Bureau of Customs and Border Protection to "U.S. Customs and Border Protection" effective March 31, 2007.

The HSA reserved customs revenue functions to the Department of the Treasury. Treasury Department Order

No. 100-16 delegated general authority vested in the Secretary of the Treasury over customs revenue functions (with certain specified exceptions) to the Secretary of Homeland Security.

Section 402 of Title IV of the Security and Accountability for Every Port Act of 2006 ("SAFE Port Act"), Public Law 109-347, established a new Office of International Trade (OT) to be headed by an Assistant Commissioner within U.S. Customs and Border Protection (CBP). Section 402(d)(2)(A) and (B) of the SAFE Port Act specifically authorized the Commissioner of CBP to transfer the assets, functions, and personnel of the Office of Strategic Trade (OST) and the Office of Regulations and Rulings (ORR) to OT. Pursuant to his authority under section 402(d)(2)(C), the Commissioner authorized the transfer of certain assets, functions, or personnel within the Office of Field Operations (OFO) to the OT.

Prior to the establishment of OT on October 15, 2006, the functions of trade policy and program development were split among three offices within CBP: the Office of Strategic Trade, the Office of Regulations and Rulings, and the Office of Field Operations. The OT consolidates the trade policy, program development, and compliance measurement functions of CBP into one

office without creating dual reporting mechanisms or overlapping and redundant management structures.

The OT includes all functions and staff from the former Office of Strategic Trade (OST) and the former Office of Regulations and Rulings (ORR), as well as designated national program managers and specialists, national analysis specialists from OFO Headquarters and the national account managers currently stationed at ports of entry.

The OT is responsible for the following functions:

(1) Providing national strategic direction to facilitate legitimate trade while protecting the American economy from unfair trade practices.

(2) Directing national enforcement responses through effective targeting of goods crossing the border as well as strict, swift punitive actions against companies participating in predatory trade practices.

(3) Coordinating with international partners to ensure effective enforcement of textile admissibility issues as well as the enforcement of free trade agreement eligibility.

(4) Cooperating with other U.S. agencies and like-minded foreign governments to achieve effective enforcement of intellectual property rights.

(5) Maintaining effective internal controls over the revenue process.

(6) Coordinating with other government agencies and international partners to identify risks to detect and prevent contaminated agricultural or food products from harming the American public or the nation's economy.

(7) Promoting trade facilitation and partnership with the importing community and trade associations by streamlining the flow of legitimate shipments and fostering corporate self-governance as a means of achieving compliance with trade laws and regulations.

(8) Managing a risk-based audit program to respond to allegations of commercial fraud and to conduct

corporate reviews of internal controls to ensure importers comply with trade laws and regulations.

(9) Providing legal tools to promote facilitation and compliance with customs, trade and border security requirements through: the issuance of all CBP regulations, legally binding rulings and decisions, informed compliance publications and structured programs for external CBP training and outreach on international trade laws and CBP regulations.

This document sets forth amendments to the CBP regulations (19 CFR chapter I) to reflect the new CBP organizational structure resulting from the creation of the Office of International Trade, as well as the transfer of the former U.S. Customs Service to DHS and the subsequent renaming of the Customs Service to CBP.

The amendments set forth in this document include the removal of certain provisions within part 171 of the CBP regulations (specifically, paragraphs (b) and (c) of § 171.62 and § 171.63) relating principally to the role of the Department of the Treasury in the consideration of supplemental petitions for relief from fines, penalties, and forfeitures. These provisions are no longer necessary or appropriate due to the transfer of CBP to DHS, the delegation of authority over certain customs revenue functions from the Department of the Treasury to the DHS, and the delegation of certain authorities from DHS to CBP as set forth in Delegation Number 7010.3 dated May 11, 2006.

The CBP regulations contain a significant number of references to offices that either no longer exist or have a different functional context. The changes set forth in this document to correct these references are non-substantive and relate to internal agency organization matters.

Inapplicability of Notice and Delayed Effective Date

Because the technical corrections set forth in this document merely conform to the Homeland Security Act of 2002

and section 402 of the SAFE Port Act, CBP finds that good cause exists for dispensing with notice and public procedure as unnecessary under 5 U.S.C. 553(b)(B). In addition, these amendments concern matters relating to agency organization and personnel which are not subject to prior notice and comment procedures pursuant to 5 U.S.C. 553(a)(2) and (b)(A). For these same reasons, pursuant to 5 U.S.C. 553(d)(3), CBP finds that good cause exists for dispensing with the requirement for a delayed effective date.

Regulatory Flexibility Act

Because this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*)

Executive Order 12866

These amendments do not meet the criteria for a "significant regulatory action" as specified in E.O. 12866.

Signing Authority

This document is limited to technical corrections of CBP regulations. Accordingly, it is being signed under the authority of 19 CFR 0.1(b)(1).

List of Subjects in 19 CFR Part 171

Administrative practice and procedure, Customs duties and inspection, Law enforcement, Penalties, Seizures and forfeitures.

Amendments to CBP Regulations

■ For the reasons given above and under the authority of 19 U.S.C. 66 and 1624, chapter I of the CBP Regulations (19 CFR chapter I) is amended as follows:

CHAPTER I—[AMENDED]

■ 1. For each section indicated in the "Section" column, remove the words indicated in the "Remove" column from wherever they appear in the section, and add, in their place, the words indicated in the "Add" column.

| Section | Remove | Add |
|------------------|--------------------------------------|--|
| 1. 4.14(c) | Entry Procedures and Carriers Branch | Cargo Security, Carriers & Immigration Branch, Office of International Trade |
| 2. 4.14(c) | Customs Form 301 | CBP Form 301 |
| 3. 4.14(c) | Customs Headquarters | CBP Headquarters |
| 4. 4.14(c) | Customs | CBP |
| 5. 4.14(f) | Entry Procedures and Carriers Branch | Cargo Security, Carriers & Immigration Branch, Office of International Trade |
| 6. 4.14(f) | Customs Headquarters | CBP Headquarters |
| 7. 4.14(f) | Customs Office of Investigations | U.S. Immigration and Customs Enforcement |
| 8. 4.14(f) | Customs | CBP |

| Section | Remove | Add |
|---------------------------------------|--|--|
| 9. 4.14(i)(1) | Customs | CBP |
| 10. 4.14(i)(1) | Entry Procedures and Carriers Branch | Cargo Security, Carriers & Immigration Branch, Office of International Trade |
| 11. 4.14(i)(1) | Customs Headquarters | CBP Headquarters |
| 12. 4.80a(d) | U.S. Customs Service | U.S. Customs and Border Protection |
| 13. 4.80a(d) | Entry Procedures and Carriers Branch | Cargo Security, Carriers & Immigration Branch, Office of International Trade |
| 14. 4.80a(d) | Customs Regulations | CBP Regulations |
| 15. 4.80b(b) | United States Customs Service | U.S. Customs and Border Protection |
| 16. 4.80b(b) | Entry Procedures and Carriers Branch | Cargo Security, Carriers & Immigration Branch, Office of International Trade |
| 17. 10.37 | Customs territory | customs territory |
| 18. 10.37 | Customs Form | CBP Form |
| 19. 10.37 | Commercial Rulings Division, Customs Headquarters | Commercial and Trade Facilitation Division, Office of International Trade, CBP Headquarters |
| 20. 10.37 | International Trade Compliance Division, Customs Headquarters | Border Security and Trade Compliance Division, Office of International Trade, CBP Headquarters |
| 21. 10.236(b)—introductory text | Customs | CBP |
| 22. 10.236(b)(1) | Customs Form 450 | CBP Form 450 |
| 23. 10.236(b)(1) | Office of Field Operations, U.S. Customs Service | Office of International Trade, U.S. Customs and Border Protection |
| 24. 10.256(b)(1) | Customs Form 449 | CBP Form 449 |
| 25. 10.256(b)(1) | Office of Field Operations, U.S. Customs Service | Office of International Trade, U.S. Customs and Border Protection |
| 26. 10.311(a) | U.S. Customs Service, Regulatory Audit Division | U.S. Customs and Border Protection, Office of International Trade, Regulatory Audit |
| 27. 10.311(a) | Customs Form 355 | CBP Form 355 |
| 28. 10.311(b) | Regulatory Audit Division | Office of International Trade, Regulatory Audit |
| 29. 10.311(b) | Customs Form 356 | CBP Form 356 |
| 30. 10.311(b) | U.S. Customs Service, Regulatory Audit Division | U.S. Customs and Border Protection, Office of International Trade, Regulatory Audit |
| 31. 10.311(c) | U.S. Customs Service, Regulatory Audit Division | U.S. Customs and Border Protection, Office of International Trade, Regulatory Audit |
| 32. 10.311(c) | Customs Form 357 | CBP Form 357 |
| 33. 12.39(b)(4) | Commercial Enforcement, Trade Compliance Division, at Customs Headquarters | Executive Director, Commercial Targeting and Enforcement, Office of International Trade, at CBP Headquarters |
| 34. 12.39(e)(1) | Customs | CBP |
| 35. 12.39(e)(1) | International Trade Compliance Division, U.S. Customs Service | Border Security and Trade Compliance Division, Office of International Trade, U.S. Customs and Border Protection |
| 36. 19.4—heading | Customs and proprietor responsibility and supervision over warehouses | CBP and proprietor responsibility and supervision over warehouses |
| 37. 19.4(b)(8)(iii) | Customs approval | CBP approval |
| 38. 19.4(b)(8)(iii) | Customs Headquarters, Office of Regulations and Rulings | CBP Headquarters, Regulations and Rulings, Office of International Trade |
| 39. 111.1 | Office of Field Operations, United States Customs Service | Office of International Trade, U.S. Customs and Border Protection |
| 40. 111.1 | prepared and filed with Customs using | prepared and filed with CBP using |
| 41. 111.1 | activities involving transactions with Customs | activities involving transactions with CBP |
| 42. 111.1 | charges assessed or collected by Customs | charges assessed or collected by CBP |
| 43. 111.1 | documents intended to be filed with Customs | documents intended to be filed with CBP |
| 44. 111.1 | data received for transmission to Customs | data received for transmission to CBP |
| 45. 111.1 | factors which Customs will consider include | factors which CBP will consider include |
| 46. 111.1 | maintenance of current editions of the Customs Regulations | maintenance of current editions of CBP Regulations |
| 47. 111.1 | Custom issuances | CBP issuances |
| 48. 111.1 | Treasury Department | Department of Homeland Security |
| 49. 111.1 | U.S. Department of the Treasury | U.S. Department of Homeland Security |
| 50. 111.5(a) | Treasury Department | Department of Homeland Security |
| 51. 111.5(b) | Treasury Department | Department of Homeland Security |
| 52. 111.13(f) | Trade Programs, Office of Field Operations, U.S. Customs Service | Trade Policy and Programs, Office of International Trade, U.S. Customs and Border Protection |
| 53. 111.13(f) | Customs | CBP |
| 54. 111.13(f) | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 55. 111.17(b) | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |

| Section | Remove | Add |
|---|---|---|
| 56. 111.17(c) | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 57. 111.19(d)(2) | Customs | CBP |
| 58. 111.19(d)(2) | Office of Field Operations | Office of International Trade |
| 59. 111.19(d)(2) | Office of Field Operations, Customs Headquarters | Office of International Trade, CBP Headquarters |
| 60. 111.19(e) | Office of Field Operations, Customs Headquarters | Office of International Trade, CBP Headquarters |
| 61. 111.19(f)—introductory text | Office of Field Operations, U.S. Customs Service | Office of International Trade, U.S. Customs and Border Protection |
| 62. 111.23(b)(2)—introductory text | Director, Regulatory Audit Division, U.S. Customs Service, 909 SE. First Avenue, Miami, Florida 33131 | Office of International Trade, Regulatory Audit, 2001 Cross Beam Dr., Charlotte, North Carolina 28217 |
| 63. 111.23(b)(2)(iii) | Director, Regulatory Audit Division, in Miami | Office of International Trade, Regulatory Audit, in Charlotte |
| 64. 111.24 | Regulatory Audit Division | Office of International Trade, Regulatory Audit |
| 65. 111.25 | Customs | CBP |
| 66. 111.26 | Treasury Department | Department of Homeland Security |
| 67. 111.27 | Regulatory Audit Division | Regulatory Audit |
| 68. 111.29(b)(1) | Customs charges | customs charges |
| 69. 111.29(b)(1) | Customs | CBP |
| 70. 111.29(b)(1) | U.S. Customs Service | U.S. Customs and Border Protection |
| 71. 111.30(c) | Office of Field Operations, U.S. Customs Service | Office of International Trade, U.S. Customs and Border Protection |
| 72. 111.31(a) | Treasury Department | Department of Homeland Security |
| 73. 111.31(b) | Treasury Department | Department of Homeland Security |
| 74. 111.32 | Treasury Department | Department of Homeland Security |
| 75. 111.34—heading | Undue influence upon Treasury Department employees | Undue influence upon Department of Homeland Security employees |
| 76. 111.34 | Treasury Department | Department of Homeland Security |
| 77. 111.38 | Treasury Department | Department of Homeland Security |
| 78. 111.51(a) | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 79. 111.66 | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 80. 111.69 | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 81. 111.70 | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 82. 111.71 | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 83. 111.72 | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 84. 111.74 | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 85. 111.75 | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 86. 111.76(b) | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 87. 111.77 | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 88. 111.81 | Secretary of the Treasury | Secretary of Homeland Security, or his designee, |
| 89. 113.14 | International Trade Compliance Division | Border Security and Trade Compliance Division, Regulations and Rulings, Office of International Trade |
| 90. 113.15 | International Trade Compliance Division | Border Security and Trade Compliance Division |
| 91. 113.38(c)(1) | International Trade Compliance Division, Customs Headquarters | Border Security and Trade Compliance Division, CBP Headquarters |
| 92. 113.38(c)(4) | International Trade Compliance Division, Customs Headquarters | Border Security and Trade Compliance Division, CBP Headquarters |
| 93. 113.38(c)(4) | Customs officer | CBP officer |
| 94. 113.38(c)(4)—(except for last sentence) ... | Customs | CBP |
| 95. 113.39(a)—introductory text | International Trade Compliance Division | Border Security and Trade Compliance Division |
| 96. 113.39(b) | International Trade Compliance Division | Border Security and Trade Compliance Division |
| 97. 133.0 | United States Customs Service | U.S. Customs and Border Protection |
| 98. 133.1(a) | U.S. Customs Service | U.S. Customs and Border Protection |

| Section | Remove | Add |
|---------------------------------------|--|--|
| 99. 133.2—introductory text | Intellectual Property Rights Branch, U.S. Customs Service | Intellectual Property Rights (IPR) & Restricted Merchandise Branch, U.S. Customs and Border Protection |
| 100. 133.2(e)—introductory text | Customs | CBP |
| 101. 133.2(f) | Customs will publish | CBP will publish |
| 102. 133.2(f) | Customs will examine | CBP will examine |
| 103. 133.2(f) | until Customs has made | until CBP has made |
| 104. 133.2(f) | Customs will publish | CBP will publish |
| 105. 133.4(a) | United States Customs Service | U.S. Customs and Border Protection |
| 106. 133.4(a) | Customs officers | U.S. Customs and Border Protection Officers |
| 107. 133.4(c) | United States Customs Service | U.S. Customs and Border Protection |
| 108. 133.6—introductory text | Intellectual Property Rights Branch | IPR & Restricted Merchandise Branch, CBP Headquarters |
| 109. 133.6(b) | United States Customs Service | U.S. Customs and Border Protection |
| 110. 133.7(a)—introductory text | Customs | CBP |
| 111. 133.7(a)—introductory text | Intellectual Property Rights Branch | IPR & Restricted Merchandise Branch |
| 112. 133.7(a)(3) | United States Customs Service | U.S. Customs and Border Protection |
| 113. 133.7(b) | Intellectual Property Rights Branch | IPR & Restricted Merchandise Branch |
| 114. 133.12—introductory text | Intellectual Property Rights Branch, U.S. Customs Service | IPR & Restricted Merchandise Branch |
| 115. 133.13(b) | United States Customs Service | U.S. Customs and Border Protection |
| 116. 133.15—heading | Term of Customs trade name recordation | Term of CBP trade name recordation |
| 117. 133.15 | Intellectual Property Rights Branch | IPR & Restricted Merchandise Branch |
| 118. 133.26 | Customs custody | CBP custody |
| 119. 133.26 | Customs Form | CBP Form |
| 120. 133.32—introductory text | Customs protection | customs protection |
| 121. 133.32—introductory text | Intellectual Property Rights Branch, U.S. Customs Service | IPR & Restricted Merchandise Branch, U.S. Customs and Border Protection |
| 122. 133.35(a) | United States Customs Service | CBP |
| 123. 133.35(a) | Intellectual Property Rights Branch | IPR & Restricted Merchandise Branch |
| 124. 133.35(b)(2) | United States Customs Service | U.S. Customs and Border Protection |
| 125. 133.36—introductory text | Intellectual Property Rights Branch | IPR & Restricted Merchandise Branch |
| 126. 133.36(b) | United States Customs Service | CBP |
| 127. 133.36(b) | made payable to the United States Customs Service | made payable to U.S. Customs and Border Protection |
| 128. 133.37(b) | Intellectual Property Rights Branch | IPR & Restricted Merchandise Branch |
| 129. 133.37(c)(3) | United States Customs Service | U.S. Customs and Border Protection |
| 130. 133.43(d)(1)(ii) | Customs Headquarters | CBP Headquarters |
| 131. 133.43(d)(1)(ii) | International Trade Compliance Division, Office of Regulations and Rulings | Border Security and Trade Compliance Division, Regulations and Rulings, Office of International Trade |
| 132. 142.3a | Customs | CBP |
| 133. 142.3a(d) | port director | Assistant Commissioner, Office of International Trade, or his designee |
| 134. 142.3a(e) | port director | Assistant Commissioner, Office of International Trade, or his designee |
| 135. 143.7(a) | Director, Trade Compliance | Executive Director, Trade Policy and Programs, Office of International Trade |
| 136. 143.8 | Director, Trade Compliance | Executive Director, Trade Policy and Programs, Office of International Trade |
| 137. 143.8 | Customs officer | CBP officer |
| 138. 146.81(b) | Director, International Trade Compliance Division | Assistant Commissioner, Office of International Trade, or his designee |
| 139. 146.83(a) | Director, International Trade Compliance Division | Executive Director, Regulations and Rulings, Office of International Trade |
| 140. 146.83(a) | Customs | CBP |
| 141. 151.12—introductory text | Customs | CBP |
| 142. 151.12(a) | Office of Field Operations, U.S. Customs Service | Office of Information and Technology, or his designee, U.S. Customs and Border Protection |
| 143. 151.12(a) | Customs | CBP |
| 144. 151.12(a) | U.S. Customs Laboratory Methods Manual | Customs and Border Protection Laboratory (CBPL) Methods |
| 145. 151.12(a) | U.S. Customs Service | U.S. Customs and Border Protection |
| 146. 151.12(a) | Customs Internet Web site: http://www.customs.gov . | CBP Web site: www.cbp.gov . |
| 147. 159.63(a) | Customs | CBP |
| 148. 159.63(a) | Office of Regulations and Rulings | Office of Finance |
| 149. 162.74(c) | Customs Headquarters, Office of Regulations and Rulings | Office of International Trade |
| 150. 162.74(c) | Customs | CBP |
| 151. 162.74(c) | Customs Headquarters | CBP Headquarters |

| Section | Remove | Add |
|-----------------------------------|--|--|
| 152. 163.5(b)(1) | Director, Regulatory Audit Division, U.S. Customs Service, 909 SE. First Avenue, Miami, Florida 33131 | Regulatory Audit, U.S. Customs and Border Protection, 2001 Cross Beam Dr., Charlotte, North Carolina 28217 |
| 153. 163.5(b)(1) | Director of the Miami regulatory audit field office | Director of Regulatory Audit, Charlotte office |
| 154. 163.5(b)(1) | Customs | CBP |
| 155. 163.11(a)(5) | Director, Regulatory Audit Division at Customs Headquarters | Executive Director, Regulatory Audit, Office of International Trade, at CBP Headquarters |
| 156. 163.11(b) | Customs | CBP |
| 157. 163.11(b) | Director, Regulatory Audit Division, U.S. Customs Service, Washington, DC 20229 | Executive Director, Regulatory Audit, Office of International Trade, U.S. Customs and Border Protection, Washington, DC 20229 |
| 158. 163.12(b)(2) | Director, Regulatory Audit Division, U.S. Customs Service, 909 SE. First Avenue, Miami, Florida 33131 | Regulatory Audit, U.S. Customs and Border Protection, 2001 Cross Beam Dr., Charlotte, North Carolina 28217 |
| 159. 163.12(b)(2) | Regulatory Audit Division, Office of Strategic Trade, U.S. Customs Service, 909 SE. First Avenue, Miami, Florida 33131 | Executive Director, Regulatory Audit, Office of International Trade, U.S. Customs and Border Protection, 1300 Pennsylvania Ave., NW., Washington, DC 20229 |
| 160. 163.12(c)(1) | Miami regulatory audit field office | Charlotte regulatory audit field office |
| 161. 163.12(c)(1) | Customs | CBP |
| 162. 163.13(d)(1) | Director, Regulatory Audit Division, U.S. Customs Service, Washington, DC 20229 | Executive Director, Regulatory Audit, Office of International Trade, U.S. Customs and Border Protection, Washington, DC 20229 |
| 163. 163.13(d)(1) | Director, Regulatory Audit Division | Executive Director, Regulatory Audit |
| 164. 163.13(d)(2) | Customs | CBP |
| 165. 163.13(d)(2) | Director, Regulatory Audit Division, U.S. Customs Service, Washington, DC 20229 | Executive Director, Regulatory Audit, U.S. Customs and Border Protection, Office of International Trade, Washington, DC 20229 |
| 166. 163.13(d)(2) | Director, Regulatory Audit Division | Executive Director, Regulatory Audit |
| 167. 171.12—heading | Petitions acted on at Customs Headquarters | Petitions acted on at CBP Headquarters |
| 168. 171.12 | Office of Regulations and Rulings, Customs Headquarters | Regulations and Rulings, Office of International Trade, CBP Headquarters |
| 169. 171.14 | Director, International Trade Compliance Division, Office of Regulations and Rulings, Customs Headquarters | Director, Border Security and Trade Compliance Division, Regulations and Rulings, Office of International Trade, CBP Headquarters, or his designee |
| 170. 171.14 | Customs | CBP |
| 171. 171.62(a) | Office of Regulations and Rulings | Border Security and Trade Compliance Division, Regulations and Rulings, Office of International Trade |
| 172. 171.62(b)—heading | Decisions of Customs Headquarters | Decisions of CBP Headquarters |
| 173. 171.62(b) | Office of Regulations and Rulings, Customs Headquarters | Regulations and Rulings, Office of International Trade, CBP Headquarters |
| 174. 171.62(b) | International Trade Compliance Division, Customs Headquarters | Border Security and Trade Compliance Division, CBP Headquarters |
| 175. Part 171, App. C, XIII | Brokers Compliance Branch, Office of Trade Compliance | Trade Policy and Programs, Office of International Trade |
| 176. 172.14 | International Trade Compliance Division, Office of Regulations and Rulings, Customs Headquarters | Border Security and Trade Compliance Division, Regulations and Rulings, Office of International Trade, CBP Headquarters |
| 177. 172.14 | Customs | CBP |
| 178. 172.42(b)—heading | Decisions of Customs Headquarters | Decisions of CBP Headquarters |
| 179. 172.42(b) | Office of Regulations and Rulings, Customs Headquarters | Regulations and Rulings, Office of International Trade, CBP Headquarters |
| 180. 172.42(b) | International Trade Compliance Division | Border Security and Trade Compliance Division, Regulations and Rulings |
| 181. 172.42(c)—heading | Authority of Assistant Commissioner | Authority of Executive Director |
| 182. 172.42(c) | Assistant Commissioner, Office of Regulations and Rulings, or his designee | Executive Director, Regulations and Rulings, Office of International Trade, or his designee |
| 183. 177.0 | United States Customs Service | CBP |
| 184. 177.0 | any Customs Service field office | any CBP field office |
| 185. 177.0 | Customs Headquarters Office other than the Office of Regulations and Rulings | CBP Headquarters Office other than Regulations and Rulings, Office of International Trade |
| 186. 177.1(d)(6) | Office of Regulations and Rulings | Regulations and Rulings, Office of International Trade |
| 187. 177.1(d)(6) | United States Customs Service | U.S. Customs and Border Protection |
| 188. 177.2(a) | Commissioner of Customs | Commissioner of Customs and Border Protection |

| Section | Remove | Add |
|--|---|---|
| 189. 177.2(a) | Office of Regulations and Rulings | Regulations and Rulings, Office of International Trade |
| 190. 177.2(a) | National Commodity Specialist Division, U.S. Customs | National Commodity Specialist Division, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection, New York, New York, 10119 |
| 191. 177.2(a) | Customs Service | Customs and Border Protection |
| 192. 177.2(b)(2)(i) | relevant Customs and related laws | relevant customs and related laws |
| 193. 177.2(b)(2)(ii)(C) | Commercial Rulings Division, U.S. Customs Service | Commercial and Trade Facilitation Division, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection |
| 194. 177.9(c) | Customs | CBP |
| 195. 177.9(c) | Commissioner of Customs | Commissioner of Customs and Border Protection |
| 196. 177.9(c) | Office of Regulations and Rulings | Regulations and Rulings, Office of International Trade |
| 197. 177.13(b)(1) | Office of Regulations and Rulings, U.S. Customs Service | Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection |
| 198. 177.22(b)—introductory text | Commercial Rulings Division | Commercial and Trade Facilitation Division, Regulations and Rulings |
| 199. 177.22(b)—introductory text | U.S. Customs Service | U.S. Customs and Border Protection |
| 200. 177.22(b)—introductory text | Customs | CBP |
| 201. 177.22(b)(3) | Customs | CBP |
| 202. 177.22(c) | Assistant Commissioner, Office of Regulations and Rulings | Executive Director, Regulations and Rulings, Office of International Trade |
| 203. 177.22(c) | U.S. Customs Service | U.S. Customs and Border Protection |
| 204. 177.26 | Director, Office of Regulations and Rulings | Executive Director, Regulations and Rulings, Office of International Trade |
| 205. 177.26 | U.S. Customs Service | U.S. Customs and Border Protection |
| 206. 181.22(b)(1) | Customs | CBP |
| 207. 181.92(a)(3) | Office of Regulations and Rulings | Regulations and Rulings, Office of International Trade |
| 208. 181.92(a)(3) | United States Customs Service | U. S. Customs and Border Protection |
| 209. 181.92(a)(6) | National Commodity Specialist Division, United States Customs Service | National Commodity Specialist Division, U.S. Customs and Border Protection |
| 210. 181.93(a) | Commissioner of Customs | Commissioner of Customs and Border Protection |
| 211. 181.93(a) | Office of Regulations and Rulings | Regulations and Rulings, Office of International Trade |
| 212. 181.93(a) | United States Customs Service, 6 World Trade Center, New York, NY 10048 | U. S. Customs and Border Protection, One Penn Plaza, 10th Floor, New York, NY 10119 |
| 213. 181.100(a)(3) | Commissioner of Customs | Commissioner of Customs and Border Protection |
| 214. 181.100(a)(3) | Office of Regulations and Rulings | Regulations and Rulings, Office of International Trade |
| 215. 181.102(a)(1)—introductory text | Customs Headquarters | CBP Headquarters |
| 216. 181.102(a)(1)—introductory text | Assistant Commissioner, Office of Regulations and Rulings, U.S. Customs Service | Executive Director, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection |
| 217. 191.7(c)—heading | Review and action by Customs | Review and action by CBP |
| 218. 191.7(c)(3) | Customs Headquarters | CBP Headquarters |
| 219. 191.7(c)(3) | Duty and Refund Determination Branch, Office of Regulations and Rulings | Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade |
| 220. 191.8(d) | Customs Headquarters | CBP Headquarters |
| 221. 191.8(d) | Duty and Refund Determination Branch, Office of Regulations and Rulings | Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade |
| 222. 191.8(e)—heading | Review and action by Customs | Review and action by CBP |
| 223. 191.8(e)—introductory text | Customs Headquarters | CBP Headquarters |
| 224. 191.8(e)(2) | Customs Headquarters | CBP Headquarters |
| 225. 191.8(e)(2) | Commercial Rulings Division | Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade |
| 226. 191.8(g)(1) | Customs Headquarters | CBP Headquarters |
| 227. 191.8(g)(1) | Duty and Refund Determination Branch, Office of Regulations and Rulings | Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade |
| 228. 191.8(g)(2)(ii) | Customs Headquarters | CBP Headquarters |

| Section | Remove | Add |
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| 229. 191.8(g)(2)(ii) | Duty and Refund Determination Branch, Office of Regulations and Rulings | Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade |
| 230. 191.11(c) | Duty and Refund Determination Branch, Office of Regulations and Rulings, Customs Headquarters | Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade, CBP Headquarters |
| 231. 191.32(c)(1) | Duty and Refund Determination Branch, Office of Regulations and Rulings | Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade |
| 232. 191.36(d) | Customs | CBP |
| 233. 191.36(d) | Customs Headquarters, Office of Field Operations, Office of Trade Operations | CBP Headquarters, Office of International Trade, Trade Policy and Programs |
| 234. 191.36(d) | Customs Headquarters | CBP Headquarters |
| 235. 191.61(d)(1) | Customs Headquarters | CBP Headquarters |
| 236. 191.61(d)(1) | Duty and Refund Determination Branch, Office of Regulations and Rulings | Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade |
| 237. 191.61(d)(2) | Customs Headquarters | CBP Headquarters |
| 238. 191.61(d)(2) | Duty and Refund Determination Branch, Office of Regulations and Rulings | Entry Process and Duty Refunds Branch, Regulations and Rulings, Office of International Trade |
| 239. 191.61(d)(3)—heading | Customs Headquarters | CBP Headquarters |
| 240. 191.61(d)(3) | Customs Headquarters | CBP Headquarters |
| 241. 191.91(g) | Customs Headquarters, Office of Field Operations, Office of Trade Operations | CBP Headquarters, Office of International Trade, Trade Policy and Programs |
| 242. 191.91(g) | Customs Headquarters | CBP Headquarters |
| 243. 191.92(h) | Customs Headquarters, Office of Field Operations, Office of Trade Operations | CBP Headquarters, Office of International Trade, Trade Policy and Programs |
| 244. 191.92(h) | Customs Headquarters | CBP Headquarters |
| 245. 191.156(d) | Office of Field Operations, Customs Headquarters | Office of International Trade, CBP Headquarters |
| 246. 191.194(a)(1) | Customs Headquarters | CBP Headquarters |
| 247. 191.194(a)(1) | Customs processing | CBP processing |
| 248. 191.194(a)(2)—introductory text | Customs review | CBP review |
| 249. 191.194(a)(2)—introductory text | Customs | CBP |
| 250. 191.194(a)(2)(i) | Customs charges | customs charges |
| 251. 191.194(a)(2)(i) | Customs | CBP |
| 252. 191.194(c) | Customs | CBP |
| 253. 191.194(d) | Customs | CBP |
| 254. 191.194(e)(1)(ii) | Customs laws and regulations | customs laws and CBP regulations |
| 255. 191.194(e)(2) | Customs | CBP |
| 256. 191.194(f)(1) | Customs Headquarters, Office of Field Operations, Office of Trade Programs | CBP Headquarters, Trade Policy and Programs, Office of International Trade |
| 257. 191.194(f)(1) | Customs Headquarters | CBP Headquarters |
| 258. 191.194(f)(2) | Customs Headquarters, Office of Field Operations, Office of Trade Programs | CBP Headquarters, Trade Policy and Programs, Office of International Trade |
| 259. 191.194(f)(2) | Customs | CBP |
| 260. Part 191, App. A, II, K | Customs Regulations | CBP Regulations |
| 261. Part 191, App. A, II, M, 6 | Customs Regulations | CBP Regulations |
| 262. Part 191, App. A, III, D, 6 | Customs Regulations | CBP Regulations |
| 263. Part 191, App. A, IV, I | Customs Regulations | CBP Regulations |
| 264. Part 191, App. A, IV, K, 6 | Customs Regulations | CBP Regulations |
| 265. Part 191, App. A, V, I | Customs Regulations | CBP Regulations |
| 266. Part 191, App. A, V, K, 6 | Customs Regulations | CBP Regulations |
| 267. Part 191, App. A, VI, I | Customs Regulations | CBP Regulations |
| 268. Part 191, App. A, VI, K, 6 | Customs Regulations | CBP Regulations |
| 269. Part 191, App. A, VII, I | Customs Regulations | CBP Regulations |
| 270. Part 191, App. A, VII, K, 6 | Customs Regulations | CBP Regulations |
| 271. Part 191, App. A, VIII, H | Customs Regulations | CBP Regulations |
| 272. Part 191, App. A, VIII, J, 6 | Customs Regulations | CBP Regulations |
| 273. Part 191, App. A, IX, M, 6 | Customs Regulations | CBP Regulations |
| 274. Part 191, App. A, X, J | Customs Regulations | CBP Regulations |
| 275. Part 191, App. A, X, L, 6 | Customs Regulations | CBP Regulations |
| 276. Part 191, App. A, XI, Y, 6 | Customs Regulations | CBP Regulations |
| 277. Part 191, App. A, XII, J | Customs Regulations | CBP Regulations |
| 278. Part 191, App. A, XII, L, 6 | Customs Regulations | CBP Regulations |
| 279. Part 191, App. A, XIII, J | Customs Regulations | CBP Regulations |
| 280. Part 191, App. A, XIII, L, 6 | Customs Regulations | CBP Regulations |
| 281. Part 191, App. A, XIV, I | Customs Regulations | CBP Regulations |
| 282. Part 191, App. A, XIV, K, 6 | Customs Regulations | CBP Regulations |
| 283. Part 191, App. B, I | Customs Headquarters | CBP Headquarters |
| 284. Part 191, App. B, I | Customs issues | CBP issues |

| Section | Remove | Add |
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| 285. Part 191, App. B, II COMPANY LETTER-HEAD (Optional). | U.S. Customs Service, Duty and Refund De-termination Branch | U.S. Customs and Border Protection, Entry Process and Duty Refunds, Regulations and Rulings, Office of International Trade |
| 286. Part 191, App. B, II COMPANY LETTER-HEAD (Optional). | Customs Regulations | CBP Regulations |
| 287. Part 191, App. B, II NAME AND ADDRESS AND IRS NUMBER (WITH SUFFIX) OF APPLICANT. | Customs Regulations | CBP Regulations |
| 288. Part 191, App. B, II PERSONS WHO WILL SIGN DRAWBACK DOCUMENTS. | Customs Regulations | CBP Regulations |
| 289. Part 191, App. B, II CUSTOMS OFFICE WHERE DRAWBACK CLAIMS WILL BE FILED—heading. | CUSTOMS OFFICE | CBP OFFICE |
| 290. Part 191, App. B, II INVENTORY PROCEDURES. | Customs Regulations | CBP Regulations |
| 291. Part 191, App. B, II BASIS OF CLAIM FOR DRAWBACK. | Customs Regulations | CBP Regulations |
| 292. Part 191, App. B, II AGREEMENTS | Customs Regulations | CBP Regulations |
| 293. Part 191, App. B, III COMPANY LETTER-HEAD (Optional). | U.S. Customs Service, Duty and Refund De-termination Branch | U.S. Customs and Border Protection, Commercial and Trade Facilitation Division, Regulations and Rulings, Office of International Trade |
| 294. Part 191, App. B, III NAME AND ADDRESS AND IRS NUMBER (WITH SUFFIX) OF APPLICANT. | Customs Regulations | CBP Regulations |
| 295. Part 191, App. B, III PERSONS WHO WILL SIGN DRAWBACK DOCUMENTS. | Customs Regulations | CBP Regulations |
| 296. Part 191, App. B, III CUSTOMS OFFICE WHERE DRAWBACK CLAIMS WILL BE FILED—heading. | CUSTOMS OFFICE | CBP OFFICE |
| 297. Part 191, App. B, III INVENTORY PROCEDURES. | Customs Regulations | CBP Regulations |
| 298. Part 191, App. B, III BASIS OF CLAIM FOR DRAWBACK. | Customs Regulations | CBP Regulations |
| 299. Part 191, App. B, III AGREEMENTS | Customs Regulations | CBP Regulations |
| 300. Part 191, App. B, IV COMPANY LETTER-HEAD (Optional). | U.S. Customs Service, Duty and Refund De-termination Branch | U.S. Customs and Border Protection, Commercial and Trade Facilitation Division, Regulations and Rulings, Office of International Trade |
| 301. Part 191, App. B, IV NAME AND ADDRESS AND IRS NUMBER (WITH SUFFIX) OF APPLICANT. | Customs Regulations | CBP Regulations |
| 302. Part 191, App. B, IV PERSONS WHO WILL SIGN DRAWBACK DOCUMENTS. | Customs Regulations | CBP Regulations |
| 303. Part 191, App. B, IV CUSTOMS OFFICE WHERE DRAWBACK CLAIMS WILL BE FILED Heading. | CUSTOMS OFFICE | CBP OFFICE |
| 304. Part 191, App. B, IV INVENTORY PROCEDURES. | Customs Regulations | CBP Regulations |
| 305. Part 191, App. B, IV BASIS OF CLAIM FOR DRAWBACK. | Customs Regulations | CBP Regulations |
| 306. Part 191, App. B, IV AGREEMENTS | Customs Regulations | CBP Regulations |
| 307. Part 191, App. B, V COMPANY LETTER-HEAD (Optional). | U.S. Customs Service, Duty and Refund De-termination Branch | U.S. Customs and Border Protection, Commercial and Trade Facilitation Division, Regulations and Rulings, Office of International Trade |
| 308. Part 191, App. B, V NAME AND ADDRESS AND IRS NUMBER (WITH SUFFIX) OF APPLICANT. | Customs Regulations | CBP Regulations |
| 309. Part 191, App. B, V PERSONS WHO WILL SIGN DRAWBACK DOCUMENTS. | Customs Regulations | CBP Regulations |
| 310. Part 191, App. B, V CUSTOMS OFFICE WHERE DRAWBACK CLAIMS WILL BE FILED—heading. | CUSTOMS OFFICE | CBP OFFICE |
| 311. Part 191, App. B, V INVENTORY PROCEDURES. | Customs Regulations | CBP Regulations |
| 312. Part 191, App. B, V BASIS OF CLAIM FOR DRAWBACK. | Customs Regulations | CBP Regulations |
| 313. Part 191, App. B, V AGREEMENTS | Customs Regulations | CBP Regulations |

PART 171—FINES, PENALTIES, AND FORFEITURES

■ 2. The authority citation for part 171, CBP Regulations, continues to read as follows:

Authority: 18 U.S.C. 983; 19 U.S.C. 66, 1592, 1593a, 1618, 1624; 22 U.S.C. 401; 31 U.S.C. 5321; 46 U.S.C. App. A. 320.

Subpart F also issued under 19 U.S.C. 1595a, 1605, 1614.

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§ 171.62 [Amended]

■ 3. Section 171.62 is amended by removing paragraphs (c) and (d).

§ 171.63 [Removed and reserved]

■ 4. Section 171.63 is removed and reserved.

Dated: October 12, 2007.

W. Ralph Basham,

Commissioner, U.S. Customs and Border Protection.

[FR Doc. E7-20471 Filed 10-18-07; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 880**

[Docket No. 2007N-0328]

Medical Devices; General Hospital and Personal Use Devices; Classification of Remote Medication Management System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the remote medication management systems into class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document entitled, "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Remote Medication Management System," which will serve as the special control for this device type. The agency is classifying this device type into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of these devices.

DATES: This final rule is effective November 19, 2007. The classification was effective June 13, 2007.

FOR FURTHER INFORMATION CONTACT: Richard Chapman, Center for Devices

and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-2585.

SUPPLEMENTARY INFORMATION:**I. What is the Background of This Rulemaking?**

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless the device is classified or reclassified into class I or class II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on September 20, 2006, classifying the INRange Remote Medication Management System in class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On September 25, 2006, INRange Systems, Inc., submitted a petition requesting classification of the INRange Remote Medication Management System under section

513(f)(2) of the act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that remote medication management systems can be classified into class II with the establishment of special controls. FDA believes that these special controls, in addition to general controls, are adequate to provide reasonable assurance of the safety and effectiveness of the device. The device is assigned the generic name "Remote Medication Management System." A remote medication management system is a device composed of clinical and communications software, a medication delivery unit, and medication packaging. The system is intended to store the patient's prescribed medications in a delivery unit, to permit a health care professional to remotely schedule the patient's prescribed medications, to notify the patient when the prescribed medications are due to be taken, to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and to record a history of the event for the health care professional. The system is intended for use as an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic.

FDA has identified the following risks to health associated with this type of device:

- Improper dosage delivered to patient,
- Cross-contamination of medications—unintended drug interactions,
- Compromised information security,
- Failure of the device—inability to deliver medication,
- Electromagnetic interference—electromagnetic emissions interfering with other medical devices or electromagnetic susceptibility causing the device to function improperly due to emissions of other devices, and
- Electrical and mechanical hazards—electrical shock, pinching.