FOR FURTHER INFORMATION CONTACT: J. Mark Reeves, Central Service Office, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, IL 60018, telephone: (847) 294–7477.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 04–19370 published on Tuesday, August 24, 2004 (69 FR 51948), established Class E airspace at Northwood, ND. An incorrect coordinate was used in the legal description. This action corrects this error.

■ Accordingly, pursuant to the authority delegated to me, the error for the Class E airspace, Northwood, ND, as published in the **Federal Register** Tuesday, August 24, 2004, (69 FR 51948), (FR Doc. 04–19370), is corrected as follows:

PART 71—[AMENDED]

§ 71.1 [Corrected]

■ 1. On page 51948, Column 3; in the legal description, change the coordinates to read; (Lat. 47°43′27″ N., long. 97°35′26″ W).

Issued in Des Plaines, Illinois on November 16, 2004.

Nancy B. Kort,

Area Director, Central Terminal Operations.

[FR Doc. 04–27091 Filed 12–9–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2004–17096; Airspace Docket No. 04–AGL–05]

Modification of Class E Airspace; South Haven, MI; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects errors contained in a final rule that was published in the **Federal Register** on Tuesday, August 24, 2004 (69 FR 51946). The final rule modified Class E airspace at South Haven, MI.

EFFECTIVE DATE: 0901 UTC, November 25, 2004.

FOR FURTHER INFORMATION CONTACT: J. Mark Reeves, Central Service Office, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, IL 60018, telephone: (847) 294–7477.

SUPPLEMENTARY INFORMATION:

History

Federal Register document 04–19372 published on Tuesday, August 24, 2004 (69 FR 51946), modified Class E airspace at South Haven, MI. An incorrect coordinate was used in the legal description and it also contained an incorrect airspace exclusion. This action corrects these errors.

■ Accordingly, pursuant to the authority delegated to me, the errors for the Class E airspace, South Haven, MI, as published in the **Federal Register** Tuesday, August 24, 2004, (69 FR 51946), (FR Doc. 04–19372), is corrected as follows:

PART 71—[AMENDED]

§ 71.1 [Corrected]

■ 1. On page 51947, Column 1; in the legal description;

■ A. Change the coordinates for Watervliet, Watervliet Community Hospital, MI Point in Space to read; (Lat. 42°11′06″ N., long. 86°15′02″ W.)

■ B. Change ''excluding that airspace within the South Bend, IN, Class E airspace area'' to read; ''excluding that airspace within the Benton Harbor, MI, Class E airspace area''.

Issued in Des Plaines, Illinois on November 16, 2004.

Nancy B. Kort,

Area Director, Central Terminal Operations.

[FR Doc. 04–27094 Filed 12–9–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 2004N–0477]

Medical Devices; General Hospital and Personal Use Devices; Classification of Implantable Radiofrequency Transponder System for Patient Identification and Health Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the implantable radiofrequency transponder system for patient identification and health information into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information.'' The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that is the special control for this device.

DATES: This rule is effective January 10, 2005. The classification was effective October 12, 2004.

FOR FURTHER INFORMATION CONTACT: Gail Gantt, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

SUPPLEMENTARY INFORMATION:

I. Background

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 and until the device is classified or reclassified into class I or 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 previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 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 that FDA 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. Within 30 days after the issuance of an order classifying the device, FDA must publish a document in the **Federal Register** announcing such classification (section 513(f)(2) of the act).