**SUPPLEMENTARY INFORMATION:**

**Background**

The Department of the Army's position on special use airspace is that it will efficiently utilize only that airspace necessary to accomplish its mission. In keeping with that policy, since the Army has closed the Seneca Army Depot there is no longer a requirement for R–5207 and the Army has requested that the FAA take action to remove the restricted area.

**The Rule**

This action amends 14 CFR part 73 by removing R–5207, Romulus, NY. The FAA is taking this action at the request of the Department of the Army. This action returns this airspace for public use.

Since this action only involves removal of restricted airspace, the solicitation of comments would only delay the return of airspace to public use without offering any meaningful right or benefit to any segment of the public. Therefore, I find that notice and public procedures under 5 U.S.C. 553(b) are unnecessary.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this action: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Section 73.52 of 14 CFR part 73 was republished in FAA Order 7400.8K, dated September 26, 2002.

**Environmental Review**

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1D, Policies and Procedures for Considering Environmental Impacts,'' and the National Environmental Policy Act of 1969. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

**List of Subjects in 14 CFR Part 73**

Airspace, Navigation (air).

**Adoption of the Amendment**

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

## PART 73—SPECIAL USE AIRSPACE

1. The authority citation for part 73 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 73.52 [Amended]**

2. § 73.52 is amended as follows:

* * * * *

**R–5207 Romulus, NY [Removed]**

* * * * *

Issued in Washington, DC, on October 31, 2002.

**Reginald C. Matthews,**

*Manager, Airspace and Rules Division.*

[FR Doc. 02–28364 Filed 11–6–02; 8:45 am]

**BILLING CODE 4910–13–P**

---

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 73

**[Docket No. FAA–2002–13525; Airspace Docket No. 02–AWP–08]**

**RIN 2120–AA66**

## Amendment to Using Agency for Restricted Area 2301W Ajo West, AZ

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This action changes the using agency of R–2301W, Ajo West, AZ. On August 12, 2002, the United States Air Force (USAF) and United States Marine Corps (USMC) requested that the FAA change the using agency for R–2301W from ''U.S. Air Force, 58th Fighter Wing Luke AFB, AZ,'' to ''Commanding Officer, USMC Air Station, Yuma, AZ,'' to reflect an administrative change of responsibility for the restricted area. This action responds to this request and does not change the boundaries; designated altitudes; time of designation; or activities conducted within the affected restricted area.

**EFFECTIVE DATE:** 0901 UTC, January 23, 2003.

**FOR FURTHER INFORMATION CONTACT:** Ken McElroy, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

**SUPPLEMENTARY INFORMATION:**

**The Rule**

This action amends title 14 Code of Federal Regulations (CFR) part 73 by changing the using agency of R–2301W, Ajo West, AZ. On August 12, 2002, the USAF and USMC requested that the FAA change the using agency for R–2301W from, ''U.S. Air Force, 58th Fighter Wing Luke AFB, AZ,'' to ''Commanding Officer, USMC Air Station, Yuma, AZ,'' to reflect an administrative change of responsibility for the restricted area. This action is an administrative change and does not affect the current boundaries; designated altitudes; time of designation; or activities conducted within the affected restricted area. Therefore, notice and public procedures under 5 U.S.C. 553(b) are unnecessary.

The FAA has determined that this action only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The coordinates for this airspace docket are based on North American Datum 83. Section 73.22 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8J, dated September 20, 2001.

**Environmental Review**

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1D, Policies and Procedures for Considering Environmental Impacts. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

**List of Subjects in 14 CFR Part 73**

Airspace, Navigation (air).

**Adoption of the Amendment**

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73, as follows:

## PART 73—SPECIAL USE AIRSPACE

1. The authority citation for part 73 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 73.23 [Amended]**

2. § 73.23 is amended as follows:

* * * * *

**R–2301W [Amended]**

By removing the words ''Using agency. U.S. Air Force, 58th Fighter Wing Luke AFB, AZ,'' and inserting the words ''Using agency. Commanding Officer, USMC Air Station, Yuma, AZ.''

* * * * *

Issued in Washington, DC, October 29, 2002.

**Reginald C. Matthews,**

*Manager, Airspace and Rules Division.*

[FR Doc. 02–28365 Filed 11–6–02; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 874

**[Docket No. 02P–0241]**

## Medical Devices; Ear, Nose, and Throat Devices; Classification of the Transcutaneous Air Conduction Hearing Aid System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the transcutaneous air conduction hearing aid system (TACHAS) into class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for the device. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997 (FDAMA). The agency is classifying this device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

**DATES:** This rule is effective November 7, 2002.

**FOR FURTHER INFORMATION CONTACT:** Eric Mann, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In accordance with section 513(f)(1) of 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 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 the FDA 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. Within 30 days after issuing an order classifying the device, FDA must publish a document in the **Federal Register** announcing the classification.

On June 21, 2002, FDA received a petition submitted under section 513(f)(2) of the act by Auric Hearing Systems Inc., seeking an evaluation of the automatic class III designation of its RetroX device. This device is intended to compensate for impaired hearing without occluding the ear canal. In accordance with section 513(f)(1) of the act, FDA issued an order automatically classifying the RetroX device 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 II. After reviewing information submitted in the petition, FDA determined that the RetroX device and substantially equivalent devices can be classified in class II with the establishment of special controls. FDA believes that class II special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

FDA has identified the following risks to health associated specifically with this type of device: (1) Infection /local inflammation, (2) injury to the ear canal, and (3) ineffective amplification.

Therefore, in addition to the general controls of the act, the device is subject to a special control guidance document entitled ''Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS); Guidance for Industry and FDA.''

FDA believes the following controls identified in the class II special controls guidance document for a TACHAS device, when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness of this type device: (1) Electro-acoustic testing, (2) fatigue testing, (3) strength test validation, (4) biocompatibility, (5) sterility, (6) clinical information, and (7) labeling to include prescription labeling in accordance with 21 CFR 801.109.

FDA believes that adherence to the class II special controls addresses the risks to health identified previously in this section of this document and provides a reasonable assurance of the safety and effectiveness of the device.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirement under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness and, therefore, the device is not exempt from the premarket notification requirements. The device is used as a wearable sound-amplifying device intended to compensate for impaired hearing without occluding the ear canal. FDA review of key design