

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA–2016–8816; Airspace
Docket No. 16–AEA–5]

**Amendment of Class E Airspace,
Ithaca, NY**

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace Designated as an Extension at Ithaca Tompkins Regional Airport, Ithaca, NY, by updating the geographic coordinates of the Ithaca VHF omnidirectional range/distance measuring equipment, (VOR/DME), and the airport, as well as changing the airport name. This is an administrative change and does not affect the boundaries or operating requirements of the airspace.

DATES: Effective 0901 UTC, November 10, 2016. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call 202–741–6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in

Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace at Ithaca Tompkins Regional Airport, Ithaca, NY.

History

In a review of the airspace for Ithaca Tompkins Regional Airport (formerly Tompkins County Airport), Ithaca, NY, the FAA found the airport name and geographic coordinates for the airport and the Ithaca VOR/DME, as published in FAA Order 7400.11A, Airspace Designations and Reporting Points, do not match the FAA's charting information for Class E Airspace Designated as an Extension to a Class D Surface Area.

Class E airspace designations are published in paragraph 6004 of FAA Order 7400.11A dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by amending Class E airspace designated as an extension at Ithaca Tompkins Regional Airport, Ithaca, NY. A minor adjustment to the geographic coordinates of the airport and the Ithaca VOR/DME is made to be in concert with the FAA's aeronautical database, as well as a name change from Tompkins County Airport to Ithaca Tompkins Regional Airport.

This is an administrative change and does not affect the boundaries, or operating requirements of the airspace, therefore, notice and public procedure under 5 U.S.C. 553(b) are unnecessary.

Regulatory Notices and Analyses

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. It, therefore: (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 proposed 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.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.5a. 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.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, effective

September 15, 2016, is amended as follows:

*Paragraph 6004 Class E Airspace
Designated as an Extension to a Class D
Surface Area.*

* * * *

AEA NY E4 Ithaca, NY [Amended]

Ithaca Tompkins Regional Airport, Ithaca, NY

(Lat. 42°29'29" N., long. 76°27'31" W.)

Ithaca VOR/DME

(Lat. 42°29'42" N., long. 76°27'35" W.)

That airspace extending upward from the surface from the 4-mile radius of the Ithaca Tompkins Regional Airport to the 5.7-mile radius of the airport; clockwise from the 329° bearing to the 081° bearing from the airport; that airspace from the 4-mile radius of Ithaca Tompkins Regional Airport to the 8.7-mile radius of the airport extending clockwise from the 081° bearing to the 137° from the airport; that airspace from the 4-mile radius of Ithaca Tompkins Regional Airport; to the 6.6-mile radius of the airport, extending clockwise from the 137° bearing to the 170° bearing from the airport; that airspace from the 4-mile radius to the 5.7-mile radius of the Ithaca Tompkins Regional Airport, extending clockwise from the 170° bearing to the 196° bearing from the airport; and that airspace within 2.7 miles each side of the Ithaca VOR/DME 305° radial extending from the 4-mile radius of Ithaca Tompkins Regional Airport to 7.4 miles northwest of the Ithaca VOR/DME. This Class E airspace area is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be published continuously in the Airport/Facility Directory.

Issued in College Park, Georgia, on September 7, 2016.

Joey L. Medders,

*Acting Manager, Operations Support Group,
Eastern Service Center, Air Traffic
Organization.*

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA-2016-N-2656]

**Medical Devices; Ophthalmic Devices;
Classification of Strabismus Detection
Device**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the strabismus detection device into class II (special controls). The special controls

that will apply to the device are identified in this order and will be part of the codified language for the strabismus detection device's classification. 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.

DATES: This order is effective September 22, 2016. The classification was applicable on June 8, 2016.

FOR FURTHER INFORMATION CONTACT:

Elvin Ng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2431, Silver Spring, MD 20993-0002, 240-402-4662, elvin.ng@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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), 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 FD&C 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 FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act

and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of "low-moderate risk" or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On December 11, 2013, RebiScan, Inc., submitted a request for classification of the Pediatric Vision Scanner under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices 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 request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 8, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 886.1342.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a strabismus detection device will need to comply with the special controls named in this final order.

The device is assigned the generic name strabismus detection device, and it is identified as a prescription device designed to simultaneously illuminate