

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

[Docket No. FAA–2021–1046; Airspace
Docket No. 21–ASO–35]

RIN 2120–AA66

**Amendment of Class E Airspace;
Ashland, KY**

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace extending upward from 700 feet above the surface at Ashland Regional Airport, Ashland, KY, by updating the geographic coordinates of the airport in the airspace legal description to coincide with the FAA’s aeronautical database. This action does not change the airspace boundaries or operating requirements.

DATES: Effective 0901 UTC, March 24, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at https://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. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: fr.inspection@nara.gov or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

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 the Class E airspace extending upward from 700 feet above the surface at Ashland Regional Airport, Ashland, KY, by updating the geographic coordinates of the airport in the airspace legal description to coincide with the FAA’s aeronautical database.

History

Class E airspace areas extending upward from 700 feet AGL above the surface are used to transition to/from the terminal or enroute environment. During a recent review of the Ashland Regional Airport, Ashland, KY, airspace, the FAA identified that the geographic coordinates of the airport were incorrect. This action updates the geographic coordinates of the airport to coincide with the FAA’s aeronautical database. This action does not change the airspace boundaries or operating requirements.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

**Availability and Summary of
Documents for Incorporation by
Reference**

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface at Ashland Regional Airport, Ashland, KY, by updating the geographic coordinates of the airport to coincide with the FAA’s aeronautical database.

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

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

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, is non-controversial and unlikely to result in adverse or negative comments. 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 only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does 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 5–6.5.a. 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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and

effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO KY E5 Ashland, KY [Amended]

Ashland Regional Airport, KY
(Lat. 38°33'16" N, long. 82°44'16" W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Ashland Regional Airport, and extending 2 miles either side of the 098° bearing from the airport extending from the 6.5-mile radius to 10.4 miles east of the airport, and extending 2 miles either side of the 278° bearing from the airport extending from the 6.5-mile radius to 10.5 miles west of the airport.

Issued in Fort Worth, Texas, on December 7, 2021.

Steven T. Phillips,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA-2021-N-0585]

**Medical Devices; Gastroenterology-
Urology Devices; Classification of the
Ingested, Transient, Space Occupying
Device for Weight Management and/or
Weight Loss**

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the ingested, transient, space occupying device for weight management and/or weight loss into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the ingested, transient, space occupying device for weight management and/or weight loss's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 10, 2021. The classification was applicable on April 12, 2019.

FOR FURTHER INFORMATION CONTACT:

April Marrone, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G218, Silver Spring, MD 20993-0002, 240-402-6510, *April.Marrone@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the ingested, transient, space occupying device for weight management and/or weight loss as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure

(Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On November 15, 2018, Gelesis, Inc. submitted a request for De Novo classification of the ingested, transient, space occupying device for weight management and/or weight loss. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the