

the NPRM to include an administrative update to the legal description of Little Rock AFB. It updates the geographic coordinates of Little Rock, AR, to lat. 34°55'03" N, long. 92°08'42" W. Because this is an administrative change that imposes no additional requirements on users of the airspace, nor does it alter the boundaries of the airspace as proposed, the FAA has determined that good cause exists to proceed with this action without recirculating the NPRM for public comment.

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 the preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 14 CFR 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 Federal Aviation Administration Order JO 7400.11], Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 5000 Class D Airspace.
* * * * *

ASW AR D Little Rock AFB, AR [Amended]

Little Rock AFB, AR
(Lat. 34°55'03" N, long. 92°08'42" W)
That airspace extending upward from the surface to and including 2,800 feet MSL within a 5.6-mile radius of Little Rock AFB airport, excluding that airspace within the Little Rock, Adams Field, AR, Class C airspace area. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.
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Paragraph 6002 Class E Surface Airspace.
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ASW AR E2 Little Rock AFB, AR [New]

Little Rock AFB, AR
(Lat. 34°55'03" N, long. 92°08'42" W)
That airspace extending upward from the surface to and including 2,800 feet MSL within a 5.6-mile radius of Little Rock AFB airport, excluding that airspace within the Little Rock, Adams Field, AR, Class C airspace area. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.
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Issued in College Park, Georgia, on June 11, 2025.

Andree C. Davis,
Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.
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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2025–0107; Airspace Docket No. 25–ASO–1]
RIN 2120–AA66

Amendment of Class D Airspace; Jupiter, FL

AGENCY: Federal Aviation Administration (FAA), DOT.
ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published by the FAA in the **Federal Register** on June 3, 2025. That final rule amended Class D airspace extending upward from the surface to and including 2,500 feet MSL within a 4.5-mile radius of William P. Gwinn Airport in Jupiter, FL, beginning at the 205° bearing from the airport clockwise to the 145° bearing, thence to the beginning point. However, there was an administrative error in the airspace description, with the incorrect state listed. Therefore, this action corrects that final rule by revising the airspace header to the correct state.

DATES: The effective date of the final rule published in the **Federal Register** on June 3, 2025 (90 FR 13571), remains 0901 UTC, August 7, 2025. 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.

FOR FURTHER INFORMATION CONTACT: Rachel Cruz, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Ave., College Park, GA 30337; Telephone (404) 305–5571.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule (90 FR 23436; June 3, 2025) amending Class D airspace at William P. Gwinn Airport in Jupiter, FL. After publication, the FAA discovered that the airspace description provided an incorrect state. Therefore, the FAA corrects the final rule as follows.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the final rule for Docket No. FAA–2025–0107, as published in the **Federal Register** on June 3, 2025 (90 FR 23436; FR Doc. 2025–09998), is corrected as follows:

1. On page 23437, in the second column, below the row of asterisks

under the section heading “Paragraph 5000 Class D Airspace.”, revise the airspace heading for Jupiter, FL to read “ASO FL D Jupiter, FL [Amended]”.

Issued in College Park, Georgia, on June 11, 2025.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2025–11200 Filed 6–17–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2023–N–4372]

Medical Devices; Exemptions From Premarket Notification: Class II Devices; Clinical Electronic Thermometers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final Order.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is publishing an order setting forth the Agency’s final determination to exempt certain class II clinical electronic thermometers from premarket notification (510(k)) requirements, subject to certain limitations. This exemption from 510(k), subject to certain limitations, is immediately in effect for such class II clinical electronic thermometers. This exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with Federal regulations. FDA is amending the classification language within the Code of Federal Regulations for certain class II clinical electronic thermometers to reflect this final determination. FDA is publishing this order in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This order is effective June 18, 2025.

FOR FURTHER INFORMATION CONTACT: Linh Lo, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993, 301–796–0463, Linh.Lo@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and its implementing

regulations in part 807, subpart E (21 CFR part 807, subpart E), persons who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use are required to submit a premarket notification to FDA. The device may not be marketed until FDA finds it “substantially equivalent” within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(1) of the FD&C Act requires that within 90 days of the date of enactment of the Cures Act, and at least once every 5 years thereafter (as FDA determines appropriate), FDA publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. FDA must provide at least a 60-day comment period for any such notice prior to issuing a final determination with respect to the devices contained in the list. Additionally, section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act, upon its own initiative or a petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA must publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and provide a 60-day comment period.

In the **Federal Register** of November 3, 2023 (88 FR 75602), FDA published a notice announcing its intent to exempt certain class II clinical electronic thermometers from premarket notification (510(k)) requirements, subject to certain limitations, and provided 60 days for interested persons to submit comments by January 2, 2024. Although FDA received no comments to the docket following a 60-day comment period, FDA is making minor modifications to clarify the limitations on exemption (see section III. B. *Partial Limitations of Exemptions*). Additionally, we provide examples to help clarify the first two partial limitations of exemption (see section III. B. *Partial Limitations of Exemptions*). This final order sets forth our final determination to exempt certain class II

clinical electronic thermometers that were the subject of the notice. Through this action, FDA is now amending the language for the identified classification regulation (21 CFR 880.2910(b)) to reflect this final determination.¹

This final order is expected to result in decreased regulatory burdens and is considered an E.O. 14192 deregulatory action.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a premarket notification (510(k)) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff” (“Class II 510(k) Exemption Guidance”) (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-class-ii-device-exemptions-premarket-notification-guidance-industry-and-cdrh-staff>). Accordingly, FDA generally considers the following factors to determine whether premarket notification is necessary for class II devices: (1) the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device’s classification. FDA may also consider that, even when exempting devices, these devices would still be subject to the limitations on exemptions.

¹ FDA notes that the “ACTION” caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to indicate that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register’s (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.