TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca. You may view this material on the Transport Canada website at *tc.canada.ca/en/aviation.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on September 10, 2026.

Hollister B. Thorson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2026–19052 Filed 9–16–26; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

[Docket No. CPSC–2026–0298]

RIN 3041–AE17

Revocation of Obsolete Rules Regarding Infant Bouncer Seats and Stationary Activity Centers

AGENCY: Consumer Product Safety Commission.

ACTION: Withdrawal of direct final rule.

SUMMARY: The U.S. Consumer Product Safety Commission (Commission or CPSC) is withdrawing a direct final rule that would remove two obsolete rules concerning infant bouncer seats and stationary activity centers that was published in the **Federal Register** on July 22, 2026, because the Commission received a significant adverse comment.

DATES: The direct final rule published on July 22, 2026 (91 FR 45992) is withdrawn effective September 17, 2026.

FOR FURTHER INFORMATION CONTACT: Daniel Taxier, Project Manager, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987–2211; email: *dtaxier@cpsc.gov.*

SUPPLEMENTARY INFORMATION: On July 22, 2026, the Commission published a direct final rule in the **Federal Register** that would remove two obsolete rules concerning infant bouncer seats and stationary activity centers because those products are subject to newer, more comprehensive mandatory safety standards issued by the Commission. 91 FR 45992. The Commission indicated in the direct final rule that if it received a significant adverse comment, the Commission would withdraw any portion of the direct final rule related to such a comment. The Commission received a significant adverse comment concerning the direct final rule and thus is withdrawing the direct final rule.[1] The Commission will consider the significant adverse comment and assess the appropriate manner in which to proceed in this matter.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2026–19065 Filed 9–16–26; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA–2025–P–5560]

Medical Devices; Exemption From Premarket Notification: Radiology Computer-Aided Detection and/or Diagnosis Devices and Computer-Aided Triage and Notification Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order setting forth its final determination regarding a partial exemption from the premarket notification requirements for radiology computer-aided detection and/or diagnosis devices and computer-aided triage and notification devices that was the subject of a notice published in the **Federal Register** of December 29, 2025. That notice announced FDA's receipt of a petition that requested exemption from the premarket notification requirements for the following generic device types when certain conditions described in the petition were met: radiological computer-assisted diagnostic software for lesions suspicious of cancer; medical image analyzers; radiological computer aided triage and notification software; and radiological computer-assisted detection and diagnosis software. FDA denied the petition in a response issued to the petitioner on April 1, 2026. FDA is publishing this order in accordance with procedures established by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This order is effective September 17, 2026.

FOR FURTHER INFORMATION CONTACT: Gugandeep Kaur, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5504, Silver Spring, MD 20993–0002, 240–402–9534.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The FD&C Act, as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) establishes three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness of the device; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act).

Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the issuance of performance standards, post-market surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions FDA (the Agency or we) deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act).

[1] The Commission voted 3–0 to publish this notification.

Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Under section 510(k) of the FD&C Act and FDA's implementing regulations in part 807, subpart E (21 CFR part 807, subpart E), persons who are required to register and 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 (510(k)) 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 to a legally marketed device that does not require premarket approval. A premarket notification is not required for devices in certain situations, such as when they have been exempted from that requirement under section 510(m) of the FD&C Act.

The 21st Century Cures Act (Pub. L. 114–255) (Cures Act) 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. After providing at least a 60-day public comment period, FDA must then publish in the **Federal Register** a list representing the final determination with respect to the devices contained in the list under section 510(m)(1)(B). 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 report under section 510(k) is not necessary to assure the safety and effectiveness of the device. FDA must publish in the **Federal Register** a notice of its intent to exempt the device, or of the petition, and provide a 60-calendar-day period for public comment. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted. In addition, within 120 days after the issuance of the notice, FDA must publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice.

II. Factors FDA Generally Considers for Exemption

There are several factors FDA may consider to determine whether a 510(k) is not necessary to assure the safety and effectiveness of a class II device. These factors are discussed in the **Federal Register** of January 21, 1998 (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 a report under section 510(k) is necessary or if an exemption would be appropriate 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 from the 510(k) requirements, these devices would still be subject to general limitations of exemptions. Specifically, even if a device is exempted from premarket notification requirements, a manufacturer of the device will still be required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into interstate commerce for commercial distribution when the device exceeds any of the limitations of exemptions described in 21 CFR parts 862–892, in the section of each part entitled ''Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act)'' (see, *e.g.,* 21 CFR 892.9).

In addition to the general limitations, partial limitations may limit an exemption from premarket notification requirements to specific devices within a device type when the Agency determines that the factors described in the **Federal Register** notice (63 FR 3142) and Class II 510(k) Exemption Guidance do not weigh in favor of exemption for all devices within a generic type of device. Where partial limitations exist, FDA has determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for devices that fall outside of the limitations.

III. Petition

On October 22, 2025, FDA received a petition requesting partial exemption from 510(k) requirements for ''radiology Computer-Aided Detection and/or Diagnosis (CAD) and Computer-Aided Triage and Notification (CADt) devices'' (the Subject CAD and CADt Devices) from Nancy Stade, J.D., of Rubrum Advising, LLC, 404 Pembroke Rd., Bala Cynwyd, PA 19004, on behalf of Harrison.ai (see Docket No. FDA–2025–P–5560). Specifically, the petition sought partial exemption for the following devices:

- Radiological computer-assisted diagnostic software for lesions suspicious of cancer, classified under § 892.2060 (21 CFR 892.2060), product code POK (CADx).
- Medical image analyzer, classified under § 892.2070 (21 CFR 892.2070), product code MYN (CADe).
- Radiological computer aided triage and notification software, classified under § 892.2080 (21 CFR 892.2080), product codes QAS and QFM (CADt).
- Radiological computer-assisted detection and diagnosis software, classified under § 892.2090 (21 CFR 892.2090), product codes QBS and QDQ (CADe/x).

All these devices currently require premarket notification under section 510(k) of the FD&C Act.

The petition requested exemption from the premarket notification requirements for the Subject CAD and CADt Devices when:

- The manufacturer had previously obtained a 510(k);
- For devices under § 892.2080 (the Subject CADt Devices), the manufacturer had at least one clearance under the same classification regulation;
- For devices under §§ 892.2060, 892.2070, or 892.2090 (the Subject CAD Devices), the manufacturer had at least

one clearance under any of those same three classification regulations;

- The manufacturer implemented ''a robust post-market plan, transparency, and training measures'' as described in the petition; and
- All existing ''special controls, quality systems, establishment registration, and device listing requirements'' remained in force.

On December 29, 2025, FDA published a notice of the petition in the **Federal Register** (90 FR 60730) and requested comments on it, in accordance with section 510(m)(2) of the FD&C Act. The comment period closed on February 27, 2026.

FDA considered the information available to the Agency, including comments from the public docket for the petition and **Federal Register** notice, and determined not to exempt devices classified under §§ 892.2060, 892.2070, 892.2080, and 892.2090 from the 510(k) requirements subject to the partial limitations of exemption proposed in the petition.[1] Accordingly, FDA responded to the petition by letter dated April 1, 2026, denying the petition within the 180-day timeframe under section 510(m)(2) of the FD&C Act.

IV. Order

As discussed in the petition response issued to the petitioner on April 1, 2026, based on FDA's review of the petition's proposed partial exemption, and in consideration of the comments submitted to the docket and FDA's own assessment of each of the four factors for exemption described in the **Federal Register** notice (63 FR 3142) and the Class II 510(k) Exemption Guidance, FDA determined that the information presented in the petition does not demonstrate that premarket notification is not necessary to assure the safety and effectiveness of the Subject CAD and CADt Devices that may be covered by the petition's proposed partial exemption. Therefore, FDA denied the petition request for partial exemption from premarket notification requirements for the Subject CAD and CADt Devices and is issuing this order setting forth the final determination. FDA's response to the petition can be found in Docket No. FDA–2025–P–5560, available at *https://www.regulations.gov/docket/FDA-2025-P-5560.*

[1] In considering the petition and comments submitted to the docket, FDA has assumed that all elements of petitioner's proposal were partial limitations on exemption that FDA may consider under section 510(m)(2) of the FD&C Act and we refer to them as partial limitations on exemption throughout this order.

Manufacturers of the Subject CAD and CADt Devices must continue to submit and receive FDA clearance of a 510(k) submission before marketing their devices, as well as comply with all other applicable requirements under the FD&C Act.

Although FDA determined that the proposal in the petition did not support a partial exemption from 510(k) requirements under section 510(m)(2) of the FD&C Act, the Agency has a longstanding commitment to develop and apply innovative approaches to the regulation of medical device software and other digital health devices to ensure their safety and effectiveness consistent with least burdensome principles. FDA supports the continued consideration of innovative and least burdensome approaches that may accelerate the availability of safe and effective devices.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final administrative order refers to previously approved collections of information found in FDA regulations. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 820 (Quality Management System Regulation) have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 (Investigational Device Exemptions) have been approved under OMB control number 0910–0078; the collections of information in part 807, subpart E (Premarket Notification Procedures), have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 822 (Postmarket Surveillance) have been approved under OMB control number 0910–0449; and the collections of information under 21 CFR part 801 (Device Labeling) have been approved under OMB control number 0910–0485.

VII. References

The following reference is on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA Guidance, ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *https://www.fda.gov/media/72685/download.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19074 Filed 9–16–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2026–1161]

RIN 1625–AA08

Special Local Regulation; Maumee River, Toledo, OH

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation (SLR) for certain navigable waters of the Maumee River near Toledo, OH. This action is necessary to provide for the safety of life on these navigable waters during the Glass City Regatta occurring on September 19, 2026. This regulation prohibits persons and vessels from entering the regulated area unless specifically authorized by the Captain of the Port, Sector Detroit or their designated representative.

DATES: This rule is effective from 7 a.m. through 4 p.m. on September 19, 2026.

ADDRESSES: To view available documents go to *https://www.regulations.gov* and search for USCG–2026–1161.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MST2 Jacob Allen, Waterways Management Division, U.S. Coast Guard Marine Safety Unit Toledo; (419) 418–6050, *D09-SMB-MSUToledo-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port