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Issued on September 10, 2026.

Hollister B. Thorson,

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

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DATES: The direct final rule published on July 22, 2026 (91 FR 45992) is withdrawn effective September 17, 2026.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

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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

¹ The Commission voted 3-0 to publish this notification.

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).