

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

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Diagnosis Devices and Computer-Aided Triage and Notification Devices

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).

Agency: Health and Human Services Department, Food and Drug Administration.

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