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ASIA EDITION

FDA reclassifies medical image analysers

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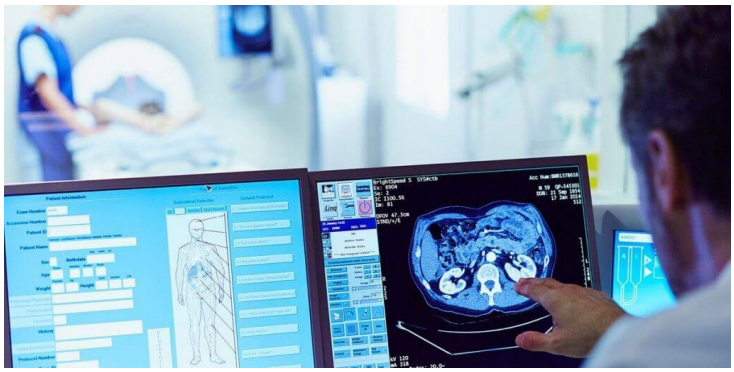
To reclassify medical image analyzers into class II devices



The US Food and Drug Administration (USFDA) has issued a final order to reclassify medical image analyzers applied to mammography breast cancer, ultrasound breast lesions, radiograph lung nodules, and radiograph dental caries detection, postamendments class III devices (regulated under product code MYN), into class II (special controls), subject to premarket notification.

These devices are intended to direct the clinician's attention to portions of an image that may reveal abnormalities during interpretation of patient radiology images by the clinician.

FDA is also identifying the special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device type.

This order is effective February 21, 2020.

The Federal Food, Drug, and Cosmetic Act (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) established 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).