First Look: FDA Proposed Rule - Radiology Devices; Reclassification of Medical Image Analyzers

Proposes to reclassify select AI-powered medical image analyzer devices to only require premarket notification to the Food and Drug Administration.

Updated last June 12, 2018 for the 06/04/2018 version of the rule.

WHAT IT DOES

The Food and Drug Administration (FDA) issued a proposed rule to reclassify medical image analyzers applied to the detection of mammography breast cancer, ultrasound breast lesions, radiography lung nodules, and radiograph dental caries. These analyzers, currently classified as class III devices under section 513 of the FD&C Act (21 U.S.C. 360c), would be reclassified to class II devices loosening requirements for premarket approval to requiring premarket notification to the FDA (requirements for each are outlined in section 513(i) (21 U.S.C. 360c(i)) and section 510(k) (21 U.S.C. 360(k)) from the Food, Drug, and Cosmetic Act, respectively). If finalized, the FDA also proposes that these newly classified devices would be identified as prescription devices to be used and labeled according to prescription labeling requirements.

With these proposed changes, the FDA also seeks to introduce new means of regulatory control to ensure the safety and effectiveness of these devices that further elucidates these devices’ identification as a prescription device. Specifically, premarket notifications for these newly classified devices must include detailed descriptions of the devices’ algorithms, datasets, and testing methodology to ensure design verification and validation. Notifications must also include performance testing of the devices indicating reduced risk of false positives and negative test results. Finally, device labeling must include detailed descriptions of who the device is intended for, risk mitigation strategies to ensure the device’s datasets are representative of the intended patient population, descriptions of how the device should be properly used, and what limitations and precautions must be considered when using the device.

RELEVANT SCIENCE

The kinds of medical image analyzers that the FDA is seeking to reclassify are called computer-assisted/aided detection (CADe) devices. CADe technology combines machine learning algorithms and datasets of previously human-reviewed medical images to detect patterns in new medical images and direct the attention of a clinician to an area on an image that require closer human-review to determine whether an abnormality is present.

STATUS

On June 6, 2018, the Food and Drug Administration published this proposed rule to the Federal Register to solicit comments from the public and interested stakeholders until August 3, 2018. After the window for comments has closed for this proposed rule, the FDA will make a final ruling considering its consideration of the comments.