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Paving the way for product authorization: FDA proposes rule to reclassify medical image analyzers

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On June 4, 2018, the U.S. Food and Drug Administration (FDA or the Agency) issued a proposed order to reclassify certain software that analyzes medical imaging from class III (premarket approval) devices to class II (subject to 510(k) premarket notification).[1] Specifically, FDA is considering the classification of software used to analyze mammography, ultrasound breast lesions, radiograph lung nodules, and radiograph dental caries. This proposal comes at the Agency's own initiative and potentially affects a wide swath of future image analysis products. If finalized, manufacturers of the specific medical image analyzers will no longer have to submit a Premarket Approval (PMA), but will instead submit a 510(k) to the Agency if there is an appropriate predicate device.

Background

Image analysis software represents one of the fastest growing medical device segments. Over the past 10 years, FDA has reclassified a number of different image analysis products, including computer-assisted/aided detection (CADe) devices. After the first approval of a CADe device in 1998,[2] FDA published two guidance documents on July 3, 2012. One guidance provided recommendations for clinical performance assessment studies.[3] The other guidance classified specific CADe devices intended to aid lung nodule and colon polyp detection from computed tomography images as class II devices.[4] In addition to these two guidance documents, FDA held meetings in March of 2008 and November of 2009 with the Radiological Devices Panel regarding the benefits and risks of these medical image analyzers.[5] Then on April 29, 2015, FDA published initial notice of its intent to consider reclassifying medical image analyzers from class III to class II.[6]

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[1] 83 FR 25598, *Radiology Devices; Reclassification of Medical Image Analyzers*, available here.
[2] R2 Technology, Inc. (now Hologic) M1000 Image Checker (P970058)
[3] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm187294.pdf. FDA intends to update the guidance document "*Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data – Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions*" to make it consistent with the reclassification upon finalization of the proposed rule.
[4] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm187315.pdf
[5] *Transcript of the FDA Radiological Devices Panel Meeting, March 4–5, 2008*, available here; *Transcript of the FDA Radiological Devices Panel Meeting, November 18, 2009*, available here.
[6] *Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection*, available here.

FDA recognized that safety profiles for existing class III CADe devices are similar to the class II CADe, noting that in the past 10 years there have been only very limited recalls associated with such product. There have also been no Medical Device Reports (MDRs) related to either the class III medical image analyzers or class II CADe devices in the past 10 years. Therefore, FDA believes that the regulatory controls applied should be similar between class III and class II CADe devices.

Reclassification of medical image analyzers

The devices that would be reclassified under this order are computer-assisted/aided detection (CADe) devices for mammography breast cancer, ultrasound breast lesions, radiograph lung nodules, and radiograph dental caries detection – with the product code MYN. The scope of the reclassification is limited to devices that are intended to assist clinical decision-making in interpreting radiological images (including mammography, radiograph, and ultrasound) by directing a clinician's attention to portions of the image that may signal abnormalities. It does not apply to devices that are intended to replace the review by a qualified radiologist or to be used for triage or to recommend diagnosis of any diseases. It also applies to prescription devices only.

If finalized, the rule will create a separate classification regulation for these devices (§ 892.2070), under which a 510(k) instead of a PMA would be required if an appropriate predicate device exists.

Proposed special controls

Class II medical devices are typically subject to so called special controls. These are controls that are specific to a product type and include requirements such as testing to specific standards or special labeling requirements. In the case of the identified image analysis products, FDA is proposing the following:

- Design verification and validation
  - A detailed description of the image analysis algorithms;
  - A detailed description of pre-specified performance testing methods and dataset(s) used to assess whether the device will improve reader performance as intended and to characterize the standalone device performance;
  - Results from performance testing that demonstrate that the device improves reader performance in the intended use population when used in accordance with the instructions for use;
  - Appropriate software documentation.

- Labeling
  - A detailed description of the patient population for which the device is indicated for use;
  - A detailed description of the intended reading protocol;
  - A detailed description of the intended user and user training that addresses appropriate reading protocols for the device;
  - A detailed description of the device inputs and outputs;
  - A detailed description of compatible imaging hardware and imaging protocols;
  - Discussion of warnings, precautions, and limitations;
  - Device operating instructions;
  - A detailed summary of the performance testing.

These requirements generally mirror what FDA has been expecting in 510(k) submissions for image analysis products in recent years.

Discussion

This proposed rule seeks to reclassify medical image analyzers applied to mammography breast cancer, ultrasound breast lesions, radiograph lung nodules, and radiograph dental caries detection from class III to class II devices, which would somewhat reduce the regulatory burden on the industry. That said, while the devices are proposed to be regulated as class II eligible for 510(k) notice, the data requirements needed to support a marketing application likely will stay the same (i.e., performance testing that demonstrate that the device improves reader performance, likely in the form of a reader study) as outlined in the special controls noted above.

In addition, the reclassification does not apply to image analyzers that are intended to triage or diagnose diseases; however, it should be noted that FDA has recently cleared two image analyzing software through the de novo pathway. In one of the recent de novo submissions (DEN180005), FDA identifies a generic type of device as Radiological Computer Assisted Detection and Diagnosis Software, which is an image processing device intended to aid in the detection, localization, and characterization of fracture, lesions, or other disease specific findings on acquired medical images (e.g. radiography, MR, CT) (CADx). The analysis is intended to inform the primary diagnostic and patient management decisions that are made by the clinical user. In another de novo (DEN170073), FDA identified the device type as Radiological Computer Aided Triage and Notification Software, which is an image processing device intended to aid in prioritization and triage of radiological medical images, by notifying a designated list of clinicians of the availability of time sensitive radiological medical images for review (CADt). These clearances further indicate FDA's willingness to lower the regulatory burden for various CADe/x/t devices.

Thus, this most recent reclassification proposal would serve to make the classification of CAD products more uniform. The proposed order and other recent reclassifications likely will help to promote innovation in diagnostic imaging through a more consistent and streamlined approach to reviewing many types of radiological computer assisted-detection, diagnosis, and triage software under the 510(k) pathway.

A docket for the proposed rule is open on the Federal Register.[7] Comments may be submitted to document number 2018-11990 until August 3, 2018.

[7] https://www.federalregister.gov/documents/2018/06/04/2018-11880/radiology-devices-reclassification-of-medical-image-analyzers

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