(vii) Detailed instructions for use.

(viii) A detailed summary of the performance testing, including: Test methods, dataset characteristics, results, and a summary of sub-analyses on case distributions stratified by relevant confounders (*e.g.,* lesion and organ characteristics, disease stages, and imaging equipment).

Dated: January 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00497 Filed 1–21–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA–2019–N–5589]

Medical Devices; Radiology Devices; Classification of the Radiological Computer Aided Triage and Notification Software

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the radiological computer aided triage and notification software into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the radiological computer aided triage and notification software's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective January 22, 2020. The classification was applicable on February 13, 2018.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 240–402–6357, *ryan.lubert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the radiological computer aided triage and notification software as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the 510(k) process, when necessary, to market their device.

II. De Novo Classification

On September 29, 2017, Viz.ai, Inc., submitted a request for De Novo classification of the ContaCT. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 13, 2018, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 892.2080.[1] We have named the

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final

Continued

generic type of device radiological computer aided triage and notification, and it is identified as an image processing device intended to aid in prioritization and triage of radiological medical images. The device notifies a designated list of clinicians of the availability of time sensitive radiological medical images for review based on computer aided image analysis of those images performed by the device. The device does not mark, highlight, or direct users' attention to a specific location in the original image. The device does not remove cases from a reading queue. The device operates in parallel with the standard of care, which remains the default option for all cases.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RADIOLOGICAL COMPUTER AIDED TRIAGE AND NOTIFICATION SOFTWARE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Failure to prioritize images for review with positive findings may result in incorrect and/or delayed patient management.	Certain design verification and validation activities identified in special control (1) and Certain labeling information identified in special control (2).
Positive notifications may result in deprioritization of review of images from other patients.	Certain design verification and validation activities identified in special control (1) and Certain labeling information identified in special control (2).
The device could be misused to analyze images from an unintended patient population or on images acquired with incompatible imaging hardware or incompatible image acquisition parameters, leading to inappropriate notifications being displayed to the user.	Certain design verification and validation activities identified in special control (1) and Certain labeling information identified in special control (2).
Device failure could lead to the absence of results, delay of results or incorrect results, which could likewise lead to inaccurate patient assessment.	Certain design verification and validation activities identified in special control (1) and Certain labeling information identified in special control (2).
The triage and notification outputs of the device are inappropriately used for primary interpretation or as an adjunct for diagnosis outside the intended use of the device.	Certain design verification and validation activities identified in special control (1) and Certain labeling information identified in special control (2).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k).

At the time of classification, radiological computer aided triage and notification are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

PART 892—RADIOLOGY DEVICES

■ 1. The authority citation for part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 892.2080 to subpart B to read as follows:

§ 892.2080 Radiological computer aided triage and notification software.

(a) *Identification.* Radiological computer aided triage and notification software is an image processing prescription device intended to aid in prioritization and triage of radiological medical images. The device notifies a designated list of clinicians of the availability of time sensitive radiological medical images for review based on computer aided image analysis of those images performed by the device. The device does not mark, highlight, or direct users' attention to a specific location in the original image. The device does not remove cases from

order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR's) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

a reading queue. The device operates in parallel with the standard of care, which remains the default option for all cases.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include:

(i) A detailed description of the notification and triage algorithms and all underlying image analysis algorithms including, but not limited to, a detailed description of the algorithm inputs and outputs, each major component or block, how the algorithm affects or relates to clinical practice or patient care, and any algorithm limitations.

(ii) A detailed description of pre-specified performance testing protocols and dataset(s) used to assess whether the device will provide effective triage (*e.g.,* improved time to review of prioritized images for pre-specified clinicians).

(iii) Results from performance testing that demonstrate that the device will provide effective triage. The performance assessment must be based on an appropriate measure to estimate the clinical effectiveness. The test dataset must contain sufficient numbers of cases from important cohorts (*e.g.,* subsets defined by clinically relevant confounders, effect modifiers, associated diseases, and subsets defined by image acquisition characteristics) such that the performance estimates and confidence intervals for these individual subsets can be characterized with the device for the intended use population and imaging equipment.

(iv) Stand-alone performance testing protocols and results of the device.

(v) Appropriate software documentation (*e.g.,* device hazard analysis; software requirements specification document; software design specification document; traceability analysis; description of verification and validation activities including system level test protocol, pass/fail criteria, and results).

(2) Labeling must include the following:

(i) A detailed description of the patient population for which the device is indicated for use;

(ii) A detailed description of the intended user and user training that addresses appropriate use protocols for the device;

(iii) Discussion of warnings, precautions, and limitations must include situations in which the device may fail or may not operate at its expected performance level (*e.g.,* poor image quality for certain subpopulations), as applicable;

(iv) A detailed description of compatible imaging hardware, imaging protocols, and requirements for input images;

(v) Device operating instructions; and

(vi) A detailed summary of the performance testing, including: test methods, dataset characteristics, triage effectiveness (*e.g.,* improved time to review of prioritized images for pre-specified clinicians), diagnostic accuracy of algorithms informing triage decision, and results with associated statistical uncertainty (*e.g.,* confidence intervals), including a summary of subanalyses on case distributions stratified by relevant confounders, such as lesion and organ characteristics, disease stages, and imaging equipment.

Dated: January 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00496 Filed 1–21–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA–2018–N–1553]

Radiology Devices; Reclassification of Medical Image Analyzers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing 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.

DATES: This order is effective February 21, 2020.

FOR FURTHER INFORMATION CONTACT: Robert Ochs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3680, Silver Spring, MD 20993–0002, 301–796–6661, *Robert.Ochs@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

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).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or II under section 513(f)(3). Section 513(f)(3) of the FD&C Act provides that FDA acting by order can reclassify the device into class I or II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide a reasonable assurance of the safety and effectiveness of the device for its intended use.

On June 4, 2018 (83 FR 25598), FDA published in the **Federal Register** a proposed order to reclassify the device type from class III to class II, subject to premarket notification. The comment period on the proposed order closed on August 3, 2018.

II. Comments on the Proposed Order

In response to the June 4, 2018, proposed order (83 FR 25598), FDA received two comments including from