

- (7) Labeling must include:
 - (i) A description of what the device measures and outputs to the user;
 - (ii) Hardware platform and operating system requirements;
 - (iii) The type of sensor data used, including specifications of compatible hardware used for data acquisition;
 - (iv) Warnings identifying sensor acquisition factors or subject conditions or characteristics that may impact measurement results;
 - (v) Information for interpretation of the measurements, including a statement that the device is not intended to replace traditional methods of diagnosis (e.g., polysomnography) nor intended to be used as an apnea monitor;
 - (vi) A summary of the clinical performance testing with the device, including both the device's overall performance as well as performance across all relevant subgroups.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2026-N-12213]

Medical Devices; General and Plastic Surgery Devices; Classification of the Software-Aided Adjunctive Diagnostic Device for Use by Physicians on Lesions Suspicious for Skin Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer 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 classification of the software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the 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 October 30, 2026. The classification was applicable on January 12, 2024.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. 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 into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (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 device 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 (see also part 860, subpart D (21 CFR part 860, subpart D)). Section

207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (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 placed 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 section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On February 2, 2023, FDA received DermaSensor Inc.'s request for De Novo classification of the DermaSensor device. 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 the safety and effectiveness of the device, 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 section 513(a)(1)(B) of the FD&C Act). 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 January 12, 2024, 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 878.1830.¹ We have named the generic type of device “software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer,” and it is identified as a prescription device that uses a software algorithm to analyze optical or other

physical properties of a skin lesion and returns a classification of the skin lesion. The device is intended for use by a physician not trained in the clinical diagnosis and management of skin cancer as an adjunctive second-read device following identification of a suspicious skin lesion. It is not for use as a standalone diagnostic and is not for use to confirm a clinical diagnosis.

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

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR SOFTWARE-AIDED ADJUNCTIVE DIAGNOSTIC DEVICE FOR USE BY PHYSICIANS ON LESIONS SUSPICIOUS FOR SKIN CANCER

Identified risks to health	Mitigation measures
False negative results, leading to failure to treat cancer and cancer progression, or false positive results, leading to unnecessary referrals and/or medical procedures.	Clinical performance testing; Postmarket surveillance; Non-clinical performance testing; and Labeling.
False results or failure to generate a result due to use error or improper device use.	Precision testing; Human factors testing; and Labeling.
False results or failure to generate a result due to device failure or malfunction.	Non-clinical performance testing; Precision testing; Software verification, validation, and hazard analysis; and Labeling.
Electrical, thermal, mechanical, or light exposure-related injury	Electrical, mechanical, and thermal safety testing; Software verification, validation, and hazard analysis; and Labeling.
Interference with other devices	Electromagnetic compatibility testing.
Adverse tissue reaction	Biocompatibility evaluation.
Infection and cross-contamination	Cleaning and disinfection validation; and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. 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 final order.

At the time of classification, software-aided adjunctive diagnostic devices for use by physicians on lesions suspicious for skin cancer 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.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this

time FDA has not made this determination for software-aided adjunctive diagnostic devices for use by physicians on lesions suspicious for skin cancer. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not normally 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 part 860, subpart D, regarding De Novo classification 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 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 management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

¹ FDA notes that the “ACTION” caption for this final order is styled as “Final amendment; final 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) 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.

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

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

■ 2. Add § 878.1830 to subpart B to read as follows:

§ 878.1830 Software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer.

(a) *Identification.* A software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer is a prescription device that uses a software algorithm to analyze optical or other physical properties of a skin lesion and returns a classification of the skin lesion. The device is intended for use by a physician not trained in the clinical diagnosis and management of skin cancer as an adjunctive second-read device following identification of a suspicious skin lesion. It is not for use as a standalone diagnostic and is not for use to confirm a clinical diagnosis.

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

(1) Data obtained from premarket clinical performance validation testing and postmarket surveillance acquired under anticipated conditions of use must demonstrate that the device performs as intended in the intended patient population, unless FDA determines based on the totality of the information provided for premarket review that data from postmarket surveillance is not required.

(i) Data must demonstrate superior accuracy of device-aided users' diagnostic characterization of the indicated lesions compared to the accuracy of unaided users.

(ii) Clinical testing must evaluate patients across a range of skin phototypes, risk factors, and anatomic areas that represents the intended use population.

(iii) Standalone device performance testing must demonstrate the accuracy of the device output relative to ground truth, including the following:

(A) Testing must demonstrate at least 90 percent sensitivity of the device output for lesions with high metastatic potential, or an alternative clinical consideration must be provided to justify lower sensitivity. Clinical justification must be provided for the reported specificity.

(B) Lesions must be selected by representative users and include a justified quantity and range of mimic lesions per diagnosis.

(C) Justification must be provided for the determination of ground truth.

(D) Testing must include a representative range of individuals with diverse risk factors (including age, body site, skin phototype, and other clinical factors), and analysis of standalone performance must include subgroup analysis by relevant risk factors.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including compatibility testing of the device software with specific signal or image acquisition hardware. Testing must include a description of compatible hardware and processes, pre-specified compatibility testing protocols, and dataset(s).

(3) Performance testing must demonstrate device precision, including repeatability and reproducibility of device performance, across operators and challenging use conditions.

(4) Performance testing must demonstrate the electrical safety, mechanical safety, thermal safety, and electromagnetic compatibility of any electrical components of the device.

(5) Performance testing must validate reprocessing instructions for reusable components of the device.

(6) The patient-contacting components of the device must be demonstrated to be biocompatible.

(7) Software verification, validation, and hazard analysis must be performed.

(8) Human factors assessment must demonstrate that the device can be safely and correctly used by intended users.

(9) Labeling must include:

(i) A summary of standalone and clinical performance testing conducted with the device that describes performance measures, including sensitivity and specificity, and statistical confidence intervals, as well as performance of the device for all clinically relevant subgroups within the intended use population;

(ii) A description of the patient population that was used in development or training of the device algorithm;

(iii) Device limitations or subpopulations for which the device may not perform as expected or for whom the device has not been validated;

(iv) Information for interpretation of the device outputs detailing the risks associated with misinterpretation of the device outputs;

(v) Warnings to avoid unsafe exposure to any energy-emitting components of the device, *e.g.*, excluding lesions close to the eye;

(vi) A statement that the device is not intended for use as a standalone diagnostic; and

(vii) Instructions for device maintenance and validated methods and instructions for reprocessing of any reusable components.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 892**

[Docket No. FDA–2026–N–12254]

Medical Devices; Radiology Devices; Classification of the Radiology Software for Referral of Findings Related to Fibrotic Lung Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the radiology software for referral of findings related to fibrotic lung disease 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 classification of the radiology software for referral of findings related to fibrotic lung disease. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the 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 October 30, 2026. The classification was applicable on January 12, 2024.

FOR FURTHER INFORMATION CONTACT: Jessica Lamb, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3672, Silver Spring, MD 20993–0002, 301–796–6167, Jessica.Lamb@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Upon request, FDA (the Agency or we) has classified the radiology software for referral of findings related to fibrotic lung disease into class II (special controls), which we have determined