May 21, 2026

Spectral MD, Inc.
Trudy Estridge
Senior Director Regulatory Affairs
2515 Mckinney Ave. Suite 1000
Dallas, Texas 75201

Re: DEN250028
Trade/Device Name: DeepView AI® System
Regulation Number: 21 CFR 878.1840
Regulation Name: Software-aided adjunctive diagnostic device for use by healthcare providers in skin wound assessment.
Regulatory Class: Class II
Product Code: SHY
Dated: June 26, 2025
Received: March 6, 2026

Dear Trudy Estridge:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the DeepView AI® System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The DeepView AI®-Burn software analyzes images obtained using the DeepView AI® System, using artificial intelligence to detect deep burn tissue (deep partial thickness and full thickness) and provides segmentation of specific areas in a burn wound by highlighting areas that are unlikely to heal within 21 days with conservative treatment alone. The absence of a highlighted region on an image indicates the absence of deep burn tissue. The system will calculate wound area measurement and percent total body surface area (TBSA) burn.
>
> DeepView AI® System with AI®-Burn software is an aid to physicians in the management of thermal burn wounds and considering various treatment plans. The DeepView AI® System should be used in conjunction with clinical assessment and not as a stand-alone diagnostic device. The device's segmentation contour does not provide definitive delineation of the deep burn margin for precise excision sizing or delineating the precise borders of non-healing tissue.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the DeepView AI® System, and substantially equivalent devices of this generic type, into Class II under the generic name software-aided adjunctive diagnostic device for use by healthcare providers in skin wound assessment.

FDA identifies this generic type of device as:

> **Software-aided adjunctive diagnostic device for use by healthcare providers in skin wound assessment.** A software-aided adjunctive diagnostic device for use by healthcare providers in skin wound assessment uses a software algorithm to analyze optical or other physical properties of a skin wound without direct wound contact and returns characterizing information that may include classification, severity, or healing potential of the skin wound. The device is intended for prescription use by healthcare providers to provide adjunctive information to be used in conjunction with clinical assessment. It is not for use as a standalone diagnostic device.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On March 6, 2026, FDA received your De Novo requesting classification of the DeepView AI® System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the DeepView AI® System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the DeepView AI® System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
False negative results, leading to delayed treatment or failure to treat appropriately, or false positive results, leading to unnecessary referrals, medical therapy (e.g., medication), and/or medical procedures (e.g., surgery)	Clinical performance testing Non-clinical performance testing Labeling

Risks to Health	Mitigation Measures
False or inaccurate results, or failure to generate a result due to use error or improper device use	Precision testing Human factors testing Labeling
False or inaccurate 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 Labeling
Electrical, thermal, or light exposure-related injury (e.g., burn, eye damage)	Electrical and thermal safety testing Software verification, validation, and hazard analysis Labeling
Interference with other devices	Electromagnetic compatibility testing

In combination with the general controls of the FD&C Act, the software-aided adjunctive diagnostic device for use by healthcare providers in skin wound assessment is subject to the following special controls:

(1) Data obtained from clinical performance validation testing must:
   (i) Demonstrate improvement of device-aided users' diagnostic characterization of the indicated wound compared to the accuracy of unaided users in the intended patient population and under anticipated conditions of use;
   (ii) Include an evaluation of patients across risk factors representative of the intended use population under the anticipated conditions of use; and
   (iii) Include standalone device performance testing that demonstrates the accuracy of the device output relative to ground truth in the intended patient population and under anticipated conditions of use, including the following:
      (A) Testing must include sensitivity and specificity of the device output with clinical justification of the reported results;
      (B) For devices that provide mapping of the wound area (e.g., wound borders, extent of wound, etc.), testing must demonstrate segmentation accuracy;
      (C) Wounds must be selected by representative users and include a justified quantity and range of wound types;
      (D) Justification must be provided for the determination of ground truth; and
      (E) 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. The following testing must be performed:
   (i) Device software must be tested for compatibility 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); and
   (ii) Performance testing must demonstrate the photobiological safety of any lamp or lamp systems.

(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 electromagnetic compatibility and electrical and thermal safety of any electrical components of the device.

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

(6) A human factors assessment must demonstrate that the device can be safely and correctly used by intended users based solely on the directions for use.

(7) Labeling must include:
- (i) A summary of standalone and clinical performance testing conducted with the device. The summary must describe 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) Information related to the limitations of device performance or subpopulations for which the device may not perform as expected;
- (iii) Information needed to facilitate interpretation of all device outputs;
- (iv) A statement that the device is not intended for use as a standalone diagnostic and is not for use to confirm a clinical diagnosis; and
- (v) Warnings to avoid unsafe exposure to any energy-emitting components of the device (e.g., excluding use of the device on wounds close to the eye).

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the software-aided adjunctive diagnostic device for use by healthcare providers in skin wound assessment they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR

4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Scott Kominsky at 301-796-9601.

Sincerely,

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Julie Morabito, Ph.D.
Director
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