January 12, 2024

DermaSensor Inc.
℅ Janice Hogan
Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: DEN230008
    Trade/Device Name: DermaSensor
    Regulation Number: 21 CFR 878.1830
    Regulation Name: Software-aided adjunctive diagnostic device for use by physicians on lesions
                        suspicious for skin cancer
    Regulatory Class: Class II
    Product Code: QZS
    Dated: January 30, 2023
    Received: February 2, 2023

Dear Janice Hogan:

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 DermaSensor, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The DermaSensor device is indicated for use to evaluate skin lesions suggestive of melanoma, basal cell carcinoma, and/or squamous cell carcinoma in patients aged 40 and above to assist in the decision regarding referral of the patient to a dermatologist. The DermaSensor device should be used in conjunction with the totality of clinically relevant information from the clinical assessment, including visual analysis of the lesion, by physicians who are not dermatologists. The device should be used on lesions already assessed as suspicious for skin cancer and not as a screening tool. The device should not be used as the sole diagnostic criterion nor to confirm clinical diagnosis of skin cancer.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the DermaSensor, and substantially equivalent devices of this generic type, into Class II under the generic name Software-aided adjunctive diagnostic devices for use by non-dermatology providers of lesions suspicious for skin cancer.

FDA identifies this generic type of device as:

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

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 February 2, 2023, FDA received your De Novo requesting classification of the DermaSensor. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the DermaSensor 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 DermaSensor 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 to health are shown in the table below. The identified risks and mitigation measures associated with the device type are summarized in the following table:

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 Labeling
False results or failure to generate a result due to use error or improper device use	Precision testing Human factors testing 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 Labeling

Electrical, thermal, mechanical, or light exposure-related injury	Electrical, mechanical, and thermal safety testing Software verification, validation, and hazard analysis Labeling
Interference with other devices	Electromagnetic compatibility testing
Adverse tissue reaction	Biocompatibility evaluation
Infection and cross contamination	Cleaning and disinfection validation Labeling

In combination with the general controls of the FD&C Act, the software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer is subject to the following special controls:

(1)   Data obtained from premarket clinical performance validation testing and post-market 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 post-market 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 un-aided 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% 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, and 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. 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)   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.

In order to satisfy special control (1) above, FDA has determined that you must collect and report postmarket surveillance data acquired under anticipated conditions of use to demonstrate that the device performs as intended when used to analyze data from the intended patient population. Specifically, you must conduct postmarket clinical validation performance testing of the DermaSensor device in patients from demographic groups representative of the U.S. population, to include populations who had limited representation of melanomas in the premarket studies (e.g., Fitzpatrick skin phototypes IV, V, and VI) or in whom sensitivity was lower than 90%, which you have proposed is the standard of care performance goal based on sensitivity of dermatologists.

FDA expects that the postmarket clinical validation performance testing will include a statistically justified study sample size to confirm that performance of the device in post-market use is not inferior to the performance observed in the pre-market study for the studied subgroup(s) or the overall population. The study should enroll a representative range of subjects with overrepresentation of patients who have Fitzpatrick skin phototypes with lower prevalence of skin cancer (e.g., Fitzpatrick skin phototypes IV, V, and VI). The study should record age, sex, socioeconomic status, race, and risk factors for skin cancer development and progression, and assess their impact on the device's effectiveness as measured by sensitivity, specificity, and/or improvement of the user's management decision.

Within 30 days of receipt of this order, you must submit a complete study protocol for your study as described above. FDA expects to work with you to approve your study protocol within 90 days of this order. Your submission should be clearly labeled as a "De Novo Postmarket Study Protocol" and submitted to the Agency as specified below. Please reference the De Novo number above to facilitate processing. If there are multiple protocols being finalized after granting of this De Novo request, please submit each protocol as a

separate submission, identified by their unique study name(s).

From the date of study protocol approval, you must meet the following timelines:

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 24 months
- 100% of subjects enrolled within 36 months

In addition, you must submit separate periodic reports on the progress of the study as follows:

- Postmarket study progress reports every year until subject enrollment has been completed, and annually thereafter, from the date of the granted De Novo letter, unless otherwise specified by FDA.
- If any enrollment milestones are not met, you must begin submitting enrollment status reports every 6 months in addition to your annual postmarket study progress reports, until FDA notifies you otherwise.
- Submit the final postmarket study report three (3) months from study completion (i.e., last subject's last follow-up date).

Each postmarket study report should be submitted to the Agency as specified below, identified as a "De Novo Postmarket Study Report" in accordance with how the study is identified above, and bearing the applicable De Novo reference number.

Be advised that failure to comply with any special control requirement, including the initiation, enrollment, completion, and reporting per the postmarket surveillance data requirements outlined above, may result in the adulteration and misbranding of your device.

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 physicians on lesions suspicious for skin cancer 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 systems (QS) regulation (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).

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).

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above De Novo number to facilitate processing.

 De Novo Postmarket Surveillence
 U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center - WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

Alternatively, documents can be submitted electronically through the CDRH Portal. For more information on the CDRH Portal, please visit https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal.

If you have any questions concerning the contents of the letter, please contact Rudy Andriani at 240-402-6030.

Sincerely,

 For
Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical
   and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health