



December 10, 2021

Medical Precision B.V.
% Akshay Kumar Harapanahalli
Official Correspondent
Medical Precision
Telfordstraat 9 - 30
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Netherlands

Re: DEN200041
Trade/Device Name: Comfort Marker 2.0.
Regulation Number: 21 CFR 892.5785
Regulation Name: Radiation Therapy Marking Device
Regulatory Class: Class II
Product Code: QRN
Dated: June 8, 2020
Received: June 22, 2020

Dear Akshay Kumar Harapanahalli:

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 Comfort Marker 2.0., a prescription device under 21 CFR Part 801.109 with the following indications for use:

The device is indicated for use for applying ink to the skin to identify the margins for radiation therapy. The device is intended to be used in clinical settings by Radiotherapy professionals.

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. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Comfort Marker 2.0., and substantially equivalent devices of this generic type, into Class II under the generic name Radiation Therapy Marking Device.

FDA identifies this generic type of device as:

Radiation Therapy Marking Device. A radiation therapy marking device is a powered device that transdermally delivers a permanent or temporary colorant to the skin for the purpose of placing marks to guide radiation therapy. This classification does not include devices with reusable or reprocessed needles or devices intended for diagnostic, therapeutic, or aesthetic use or to deliver other products for these uses.

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 June 22, 2020, FDA received your De Novo requesting classification of the Comfort Marker 2.0. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Comfort Marker 2.0. 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 Comfort Marker 2.0. 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 an adverse tissue reaction, infection, needle stick injury to provider, cross-contamination, electrical shock or thermal injury, and potential interference with other devices. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Cross contamination and infection	Reprocessing validation Sterilization validation Non-clinical performance testing Shelf-life testing Labeling
Needle stick injury to provider	Non-clinical performance testing Labeling
Device and/or software failure leading to ineffective marking	Clinical performance testing Non-clinical performance testing Software validation, verification, and hazard analysis Labeling
Electrical shock or electromagnetic interference with other devices	Electromagnetic compatibility testing Electrical safety testing Labeling

In combination with the general controls of the FD&C Act, the radiation therapy marking device is subject to the following special controls:

Special Controls

- (1) Design verification and validation must include:
 - (i) Documentation of performance data from studies that demonstrate:
 - (A) The indicated colorant is compatible with the device and its method of delivery;
 - (B) The device can reproducibly deliver the indicated colorant with the specifications described; and
 - (C) The length of time that compatible colorants remain visible on the skin following device application.
 - (ii) Documentation of performance data from studies that demonstrate:
 - (A) Accuracy and reproducibility of needle penetration depth;
 - (B) Device protection from cross-contamination, including fluid ingress protection;
 - (C) Adequacy of the cleaning and disinfection instructions to ensure that the reusable components of the device can be cleaned and disinfected; and
 - (D) The sterility of all patient-contacting components (e.g., safety needle).
 - (iii) Documentation of performance data from studies that demonstrate electrical safety and electromagnetic compatibility (EMC) of all electrical components of the device.
 - (iv) Documentation of performance data from studies that demonstrate continued sterility, package integrity, and device functionality over the intended shelf life.
 - (v) Documentation of software verification, validation, and hazard analysis.
- (2) The labeling required under 21 CFR 801.109(c) must include:
 - (i) An explanation of the device and the mechanism of operation;
 - (ii) Validated methods and instructions for reprocessing of any reusable components;
 - (iii) Disposal instructions; and
 - (iv) A shelf life for all sterile components.

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

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 Radiation Therapy Marking Device 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).

If you have any questions concerning the contents of the letter, please contact Lynne Fairbent at 301-796-4817.

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health