November 26, 2025

MuReva Phototherapy Inc.
℅ Kristin Zielinski Duggan
Partner
Hogan Lovells, US, LLP
555 Thirteenth St, NW
Washington, District of Columbia 20004

Re: DEN240077
Trade/Device Name: MuReva OM™
Regulation Number: 21 CFR 872.5595
Regulation Name: Intraoral phototherapy device
Regulatory Class: Class II
Product Code: SGQ
Dated: December 23, 2024
Received: December 23, 2024

Dear Kristin Zielinski Duggan:

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

> The MuReva OM™ is intended for use during radiation treatment to lower the severity of oral mucositis and associated complications with radiation induced oral mucositis in adult patients receiving radiation to less than 75% of their oral cavity with or without chemotherapy. This device is prescription use only (Rx only).

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the MuReva OM™, and substantially equivalent devices of this generic type, into Class II under the generic name intraoral phototherapy device.

FDA identifies this generic type of device as:

> **Intraoral phototherapy device**. An intraoral phototherapy device is an intraoral, non-ionizing, light-based device that is intended for non-surgical treatment of oral conditions such as oral mucositis.

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 December 23, 2024, FDA received your De Novo requesting classification of the MuReva OM™. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the MuReva OM™ 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 MuReva OM™ 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
Optical radiation performance outside of specification leading to treatment ineffectiveness	Clinical performance data Non-clinical performance testing Software validation, verification, hazard analysis Electrical safety testing Electromagnetic compatibility (EMC) testing Labeling
Thermal or optical injury	Non-clinical performance testing Electromagnetic compatibility (EMC) testing Electrical safety testing Software validation, verification, hazard analysis Labeling
Device failure/malfunction leading to harm or injury to the patient (e.g., laceration, obstruction, discomfort)	Non-clinical performance testing
Software malfunction	Software verification, validation, and hazard analysis
Electrical shock or interference	Electrical safety testing Electromagnetic compatibility (EMC) testing Wireless coexistence testing
Adverse tissue reaction	Biocompatibility evaluation
Infection and cross-contamination	Reprocessing validation

In combination with the general controls of the FD&C Act, the intraoral phototherapy device is subject to the following special controls:

(1) Clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. Data must evaluate treatment outcomes for the specified indications for use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:
   (i) Optical radiation testing, including:
      (A) Wavelength specifications, output radiant power, irradiance range, spatial beam distribution and homogeneity, and radiant dose range delivered to oral cavity treatment areas;
      (B) Testing of safety features protecting against optical radiation hazards and unintended output;
   (ii) Thermal testing of operating temperatures for all conditions of use throughout treatment duration; and
   (iii) Testing of material integrity and mechanical durability for the expected lifecycle duration.

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

(4) Performance testing must demonstrate electrical safety, electromagnetic compatibility (EMC), and wireless coexistence of the device in the intended use environment.

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

(6) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.

(7) Labeling must include:
   (i) Information on the patient population for which the device has demonstrated to be effective based on clinical performance data for the specified indications for use;
   (ii) Identification of the optical radiation output specifications, including peak wavelength, output radiant power, mode of operation (e.g., continuous or pulsed), and optical radiation safety classification;
   (iii) A recommendation of the treatment schedule including the duration per use, daily frequency, and total treatment period; and
   (iv) Warnings to avoid eye exposure and instructions regarding appropriate eye protection by both the operator and the patient.

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 intraoral phototherapy 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).

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 Lauren Giles at 301-796-9552.

Sincerely,

SRINIVAS NANDKUMAR -S

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
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