March 27, 2024

Medline Industries, Inc
Claire Pigman
Director, Regulatory Affairs
Three Lakes Drive
Northfield, Illinois 60093

Re: DEN210049
Trade/Device Name: Medline ART Skin Harvesting System
Regulation Number: 21 CFR 878.4795
Regulation Name: Semi-automated autologous skin graft harvesting and application device
Regulatory Class: Class II
Product Code: QYK
Dated: October 15, 2021
Received: October 19, 2021

Dear Claire Pigman:

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 Medline ART Skin Harvesting System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The ART (Autologous Regeneration of Tissue) Skin Harvesting System is intended for the harvesting and application of autologous, full-thickness micrografts for wounds where autologous skin grafting would be appropriate.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Medline ART Skin Harvesting System, and substantially equivalent devices of this generic type, into Class II under the generic name semi-automated autologous skin graft harvesting and application device.

FDA identifies this generic type of device as:

> **Semi-automated autologous skin graft harvesting and application device**. A semi-automated autologous skin graft harvesting and application device is a handheld electromechanical surgical instrument that extracts autologous skin graft tissue from a healthy donor skin site and deposits it to a recipient site. The device extraction and deposition functions are automated and are activated by the user. The device is not intended for treatment of full-thickness burns.

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 October 19, 2021, FDA received your De Novo requesting classification of the Medline ART Skin Harvesting System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Medline ART Skin Harvesting 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 FDA has determined that, for the previously stated indications for use, the Medline ART Skin Harvesting 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**
Delay in healing	*In vivo* performance testing
Device malfunction resulting in injury	Performance testing Software verification, validation, and hazard analysis Electrical safety testing
Failure of the user to select an adequate donor site resulting in increased donor site morbidity	Labeling
Infection	Sterilization validation Reprocessing validation Shelf life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Interference with other medical devices resulting in malfunction of either device	Electromagnetic compatibility testing Electrical safety testing Software verification, validation, and hazard analysis Wireless coexistence testing Labeling
User error resulting in injury	Human factors evaluation Labeling

In combination with the general controls of the FD&C Act, the semi-automated autologous skin graft harvesting and application device is subject to the following special controls:

(1) *In vivo* performance testing must demonstrate that the device performs as intended under anticipated conditions of use in a clinically relevant wound model, including evaluation of normal wound healing.

(2) Performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
   (i) Ability of the device to extract target tissue to the intended depth;
   (ii) Ability of the device to extract target tissue without damage to underlying structures; and
   (iii) Ability of the device to deposit extracted tissue at the recipient site.

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

(4) Software validation, verification, and hazard analysis must be performed for any software components of the device.

(5) Performance data must support the electrical safety, electromagnetic compatibility (EMC), and wireless coexistence of the device.

(6) Performance data must validate the reprocessing instructions for the reusable components of the device.

(7) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(8) Performance data must support the shelf life of sterile device components by demonstrating package integrity and device functionality over the identified shelf life.

(9) Human factors/usability evaluation must be performed to confirm that the user can correctly use the device based solely on the device labeling.

(10) Labeling must include:
   (i) Instructions on preparation of donor sites and treatment of recipient sites prior to and following use of the device;
   (ii) Validated reprocessing instructions for any reusable device components; and
   (iii) A shelf life.

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 semi-automated autologous skin graft harvesting and application 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 John Azeke at John.Azeke@fda.hhs.gov

Sincerely,

Binita S. Ashar -S

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