



AVITA Medical Americas, LLC
Sandra Aprahamian
Director, Regulatory Affairs
28159 Avenue Stanford, Suite 220
Valencia, CA 91355

June 9, 2021

Re: BP 170122/287

Trade/Device Name: RECELL® Autologous Cell Harvesting Device

Product Code: QCZ

Filed: December 14, 2020

Amended: March 10, 2021, March 24, 2021, April 6, 2021, April 29, 2021, May 27, 2021

Dear Ms. Aprahamian:

The Center for Biologics and Evaluation Research (CBER) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement for the RECELL® Autologous Cell Harvesting Device, where you request to modify the Indications for Use to support the use of RECELL in combination with meshed autografting for the treatment of acute full-thickness thermal burn wounds 1) in patients 18 years of age and older, and with >50% of total body surface area (TBSA), and 2) in patients between 28 days and 17 years of age.

This device is indicated for the treatment of acute thermal burn wounds. The device is used by an appropriately-licensed healthcare professional at the patient's point of care to prepare autologous RES® Regenerative Epidermal Suspension for direct application to acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients. We are pleased to inform you that the PMA supplement is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device.

Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 18-months after the date of manufacture when the device is shipped and stored under ambient conditions.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system>.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" <https://www.fda.gov/media/81431/download>.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are

required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems> and on combination product post-marketing safety reporting is available at (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>.

CBER does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CBER will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CBER Internet Home Page located at <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/premarket-approval-pma-process-cber>. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit a Product Correspondence to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the Product Correspondence.

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

Due to COVID-19 closure, the Document Control Center (DCC) will not process any submissions received by mail or courier including submissions provided on paper and electronic media (e.g., CDs, USB drives) after Wednesday, April 29, until further notice.

Submission previously submitted by mail can still be sent through the [Electronic Submission Gateway](#) (ESG) or in some cases by e-mail. CBER strongly encourages sending submissions (under 10GB) through FDA's preferred secure method of transmission, the ESG. Commercial applicants and sponsors should continue to submit in standard eCTD format using the ESG as described in guidance for industry, [Providing Regulatory Submission in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications](#).

Applicants and sponsors exempt from eCTD submission requirements (e.g., research³) may submit a PDF version to the DCC via email at CBERDCC_eMailSub@fda.hhs.gov. However, we draw your attention to the option of submission via the ESG using the alternate (non-eCTD) format, as described in draft guidance [Providing Regulatory Submissions in Alternate Electronic Format](#).

Applicants and sponsors of biological product submissions that are exempt from eCTD requirements, as well as applicants and sponsors of device submissions who are experiencing difficulty sending submissions using the preferred secured methods, or do not have an ESG account may send submissions (under 150MB) via email at CBERDCC_eMailSub@fda.hhs.gov. We will accept these submissions through this email option only during the COVID-19 public health emergency.

If you have any questions concerning this approval order, please contact Nevitt Morris at 240-402-8269 or Nevitt.Morris@fda.hhs.gov.

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation
and Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research