



AVITA Medical LLC  
Attention: Sandra Aprahamian  
28159 Avenue Stanford, Suite 220  
Valencia, CA 91355

**Original PMA Approval Order**  
June 16, 2023

Re: BP220799

Trade/Device Name: RECELL Autologous Cell Harvesting Device  
(Model Number: AVRL0102)

Product Code: QWY

Filed: December 19, 2022

Amended: December 30, 2022, January 11, 2023, January 17, 2023, January 20, 2023, February 6, 2023, February 13, 2023, March 1, 2023, March 2, 2023, March 6, 2023, March 13, 2023, March 22, 2023, April 25, 2023, May 1, 2023, May 18, 2023, May 19, 2023, June 1, 2023, June 5, 2023, June 7, 2023, June 12, 2023, June 14, 2023, June 15, 2023, June 16, 2023.

Dear Ms. Aprahamian:

The Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the RECELL Autologous Cell Harvesting Device (Model Number: AVRL0102). This device is indicated for repigmentation of stable depigmented vitiligo lesions in patients 18 years of age and older. The RECELL Device is intended for use by an appropriately licensed and trained healthcare professional at the patient's point-of-care for the safe and rapid preparation of Spray-On Skin Cells from a small sample of a patient's own skin. The suspension of Spray-On Skin Cells is suitable for application to skin resurfaced by an ablative laser. A portion of the suspension of Spray-On Skin Cells may also be applied to the donor site. We are pleased to inform you that the PMA 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 24-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. I

You have agreed to provide the following non-clinical information Post-Approval Study Reports, which may be followed by a PMA supplement where applicable.

### **Human Factors Validation**

1. AVITA Medical will conduct additional Human Factors (HF) validation testing with participants, use environments, and uses that are realistically representative of the actual population of intended users (healthcare professionals who specialize in dermatology), use environments (e.g., procedure rooms), and uses of the new RECELL Device for vitiligo. This additional HF validation testing will be performed according to the protocol from the existing HF validation conducted under BP170122 with any necessary modifications related to the participants, use environments, and uses. AVITA Medical will include in the validation testing protocol a comprehensive analysis of the intended users, use environments, and uses for the RECELL Device for vitiligo. AVITA Medical will submit the human factors engineering (HFE) report, inclusive of new HF validation data to support use safety and effectiveness of the RECELL Device for vitiligo, as a Post-Approval Study (PAS) Report within 1-year of the approval order.

Be advised that failure to comply with any post-approval requirement constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

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/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm089793.htm>. 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.

U.S. Food and Drug Administration  
Center for Biologics Evaluation and Research  
Document Control Center  
10903 New Hampshire Ave.  
WO71-G112  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Julia Russell at 240-402-8122 or [Julia.Russell@fda.hhs.gov](mailto:Julia.Russell@fda.hhs.gov).

Sincerely,

Celia Witten, PhD, MD  
Acting Director  
Division of Clinical Evaluation General Medicine  
Office of Clinical Evaluation  
Office of Therapeutic Products  
Center for Biologics Evaluation and Research