September 20, 2018

Avita Medical Americas, LLC
Attention: Ron Lagerquist

Senior Director RA/QS
28159 Avenue Stanford, Suite 220
Valencia, CA 91355

Re:BP170122

Trade/Device Name: RECELL® Autologous Cell Harvesting
Device Filed: September 28, 2017
Amended: September 28, 2017, October 6, 2017, October 16, 2017, October 25, 2017, November 15, 2017, December 4, 2017, December 18, 2017, June 18, 2018, July 2, 2018, July 23, 2018, July 30, 2018, August 8, 2018, August 13, 2018, August 14, 2018, August 20, 2018, August 21, 2018, August 22, 2018, August 23, 2018, August 23, 2018, August 24, 2018, August 27, 2018, August 29, 2018, August 30, 2018, August 30, 2018, August 31, 2018, September 5, 2018, September 6, 2018, September 10, 2018, September 12, 2018, September 14, 2018, September 17, 2018, September 19, 2018

Product Code: QCZ

Dear Mr. Lagerquist:

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. This device is indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. The RECELL® Device is used by an appropriately-licensed healthcare professional at the patient's point-of-care to prepare autologous Regenerative Epidermal Suspension (RES™) for direct application to acute partial-thickness thermal burn wounds or application in combination with meshed autografting for acute full-thickness thermal burn wounds. 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 the 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 6-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. This report, identified as "**Annual Report**" and bearing the applicable 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.

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

(b) (4) Assay Validation

1. Avita will perform (b) (4) Assay validation (specificity, accuracy, linearity, repeatability, intermediate precision, range, and ruggedness) at each laboratory that conducts the (b) (4) assay using a statistically meaningful number of samples of the RECELL® Enzyme obtained from multiple production lots. Results obtained by each participating laboratory should be comparable when testing the same sample using the validated assay. Avita will submit the testing protocol(s) and complete (b) (4) assay validation test report(s) as a Post-Approval Study Report by February 18, 2019.

Enzyme Stability and RECELL® Device Shelf Life

2. RECELL® Enzyme stability determines RECELL® device shelf life. Avita Medical will conduct a prospective RECELL® Enzyme stability study that involves assessment of multiple attributes ((b) (4), appearance, dissolution time, container closure/integrity, (b) (4), enzyme activity, and bacterial endotoxin). (b) (4) samples of enzyme from (b) (4) separate production lots ((b) (4) individual samples per lot) that have been subjected to (b) (4), including worst case sterilization, atmospheric conditioning, simulated shipping, and real time aging under ambient conditions will be evaluated according to the stability study protocol to re-affirm the current 6-month RECELL® device shelf life. Avita Medical will submit the results of the executed stability

study re-affirming 6-month stability as a Post-Approval Study Report by September 20, 2019 and as additional 30-Day Notices for further shelf life extensions.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identifier (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, http://www.fda.gov/udi.

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" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm.

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 postmarketing 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 become 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm and on combination product postmarketing safety reporting is available at (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the postmarketing 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 http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

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 device 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 an amendment to this PMA submission with copies 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 amendment.

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 –
WO71-G112
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Jean Gildner at240-402-8296 or Jean.Gildner@fda.hhs.gov.

Sincerely,

Wilson W. Bryan,MD
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and
Research