



February 28, 2022

Saluda Medical Pty Ltd
Monica Early
Head of Regulatory Affairs
407 Pacific Highway Level 1
Artarmon, NSW 2064 Australia

Re: P190002

Trade/Device Name: Saluda Medical Evoke[®] SCS System

Product Code: LGW

Filed: January 22, 2019

Amended: February 13, 2019, September 30, 2019, March 30, 2020, June 25, 2020, June 17, 2021,
February 28, 2022

Dear Monica Early:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Evoke[®] SCS System. This device is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain. 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 two years for the closed loop stimulator (CLS) and one year for all other sterile system components.

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.

You have agreed to provide the following non-clinical information in a PMA report, which may be followed by a PMA supplement where applicable.

1. **Identification of chemicals:** Saluda will more "confidently" identify (consistent with USP <1663>) the two remaining tentative chemicals with structural information suitable for a toxicological risk assessment and provide test reports to the agency for review.

The names of the remaining tentative chemicals were submitted to the agency in A006, received by CDRH on February 28, 2022.

2. **Release kinetics study design:** Saluda will provide release kinetics studies for each chemical that includes the following:
 - a. 180-day release kinetic study using 100% acetonitrile as the extraction solvent and an Analytical Evaluation Threshold (AET) based on a Dose-Based Threshold (DBT) of 1.5ug/d.
 - b. Justification for assessment timepoints through 180 days (to include daily assessments with pre-specified rules for when to allow less frequent assessment, and justification for periodic assessments and how late bolus release will be investigated, as average daily estimates and cumulative release cannot be used in the toxicological risk assessment).
 - c. Detailed information on how the chemical analysis will be conducted for the chemicals of interest (and their possible degradation/interaction products):
 - d. Detailed information to:
 - i. Justify the surrogate standard(s) that will be used for each chemical of interest (e.g., if chemicals can only be tentatively identified at the time the release kinetic study is conducted, multiple standards for quantification may be helpful), including detector settings (e.g. ions monitored in MS detection).
 - ii. Provide the calibration range and justification for the calibration range.

The names of the remaining chemicals of interest were submitted to the agency in A006, received by CDRH on February 28, 2022.

3. **Toxicological risk assessments:** Saluda will provide updated toxicological risk assessments based on the release kinetics study (for all chemicals) using the quantity for each targeted chemical reported from each assessment time point in the release kinetic study (i.e., from each reported amount, not from an average daily estimate or the cumulative amount for each chemical) as a worst-case exposure.
4. **Timeline:** We expect that the additional information to satisfy the Conditions for Approval will be submitted for review by the agency through a separate PMA Report, (which may be followed by a PMA supplement where applicable) within 1.5 years of the date of the approval letter.

Be advised that failure to comply with any post-approval requirements, including the identification data, toxicological risk assessment, release kinetic study protocol requirements, and timeline outlined above, 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>.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH 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 CDRH Internet Home Page located at

<https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals>. 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 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 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 Devices and Radiological Health

Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Kaitlin Olsen at Kaitlin.Olsen@fda.hhs.gov.

Sincerely,

Vivek J. Pinto -S

Vivek Pinto, PhD

Director

DHT5B: Division of Neuromodulation
and Physical Medicine Devices

OHT5: Office of Neurological
and Physical Medicine Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health