



March 18, 2026

LivaNova USA, Inc.
Bijal Patel-Jain
Director, Regulatory Affairs
100 Cyberonics Blvd.
Houston, Texas 77058

Re: P250013

Trade/Device Name: aura6000™ system

Product Code: MNQ

Filed: April 25, 2025

Amended: October 10, 2025, November 21, 2025, December 18, 2025

Dear Bijal Patel-Jain:

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 aura6000™ system. This device is indicated for the reduction of apneas, hypopneas, or both in adult patients with moderate to severe obstructive sleep apnea (OSA), defined as an apnea-hypopnea index (AHI) of ≥ 15 and ≤ 65 . The aura6000™ system is intended for patients who failed, do not tolerate, or are ineligible to be treated with current standard of care treatments such as positive airway pressure (PAP), oral appliances (e.g. mandibular advancement device), or pharmacotherapy.

PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as:

- Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night), or
- Unwillingness to use PAP (e.g., a patient returns the PAP system after attempting to use it).

Based upon the information submitted, 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 available 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 all other applicable requirements, including those governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved as follows:

1. Implantable Pulse Generator: 1 year.
2. Leads: 2 years.

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 must 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, under 21 CFR 814.82(a)(9), 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 must obtain approval of your post-approval study (PAS) protocol(s) within 60 days from the date of this order. Within 30 days of your receipt of this letter, you must submit PMA supplements that include complete protocols of your post-approval studies described below. Your PMA supplements should be clearly labeled as a "PMA Post-Approval Study Protocol" as noted below and submitted to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below.

1. **Extended Follow-up of the Premarket Cohort (OPSPREY Study):** This study will be conducted as a multi-center, prospective, observational, open-label, long-term follow-up of subjects who completed the M13 visit of the OSPREY clinical trial. This study is designed to evaluate the long-term safety and efficacy of the aura6000™ system in up to 150 subjects previously implanted under the premarket study, with follow-up extending to 5 years post-surgery (approximately 60 months on therapy for the active group and 4.5 years on therapy for the control group). The primary safety objective is to evaluate long-term device-related and procedure-related adverse events, with relationship to procedure and device. The primary efficacy objective is to evaluate change in AHI (Apnea Hypopnea Index) relative to the pre-therapeutic baseline in subjects implanted with the aura6000™ system annually based on home sleep test (HST) and/or polysomnography (PSG) data with success criteria defined as achieving a 50% responder rate in evaluable subjects for AHI

responder criteria ($\geq 50\%$ reduction and $AHI < 20$). Secondary assessments include changes in sleep-disordered breathing and quality of life outcomes from pre-therapeutic entry to annually thereafter through validated instruments including decrease in ODI between pre-therapeutic timepoint and annual visit, change in ESS (Epworth Sleepiness Scale) between pre-therapeutic timepoint and annual visit, change in FOSQ (Functional Outcomes of Sleep Questionnaire) between pre-therapeutic timepoint and annual visit, Clinical Global Impression Severity (CGI-S) at pre-therapeutic timepoint, and Clinical Global Impression Improvement (CGI-I) annually thereafter. All adverse events will be summarized descriptively, and subjects will undergo biannual impedance checks to assess IPG function.

- 2. New Enrollment Study (Post-Approval Study):** This study will be initiated upon commercial introduction of the device as a multicenter, prospective, single-arm, post-approval study to demonstrate the long-term safety and effectiveness of the device in treating subjects diagnosed with moderate to severe obstructive sleep apnea (OSA), defined as an apnea-hypopnea index (AHI) of ≥ 15 and ≤ 65 , who have failed, do not tolerate, or are ineligible to be treated with current standard of care treatments such as positive airway pressure (PAP), oral appliances (e.g., mandibular advancement device), or pharmacotherapy. The study is planned to enroll to a target of 160 implanted subjects at a minimum of 10 US sites, with baseline evaluation, device implantation, and therapy activation at 4 to 6 weeks post-implantation. Subjects will then have follow-up visits at 6 months, 12 months, and every 6 months thereafter for up to 5 years. Safety events will be assessed through collection of all device-related and procedure-related adverse events (AEs) or serious adverse events (SAEs) including device explants due to infection, malfunction, or repositioning requiring surgery, that will be captured at all scheduled and unscheduled visits. The safety of the device will be monitored relative to performance observed in the premarket experience from the OSPREY study including the rate of device-related SAEs of 10.3% through Month 13. The primary efficacy objectives include therapy efficacy measured by improvement in OSA severity (AHI) using annual in-lab polysomnography at years 1, 2, 3, 4, and 5, with success criteria defined as achieving a 50% responder rate in evaluable subjects for AHI responder criteria ($\geq 50\%$ reduction and $AHI < 20$). Secondary endpoints will include ODI responder rate ($\geq 50\%$ reduction from baseline), subject satisfaction, change in Functional Outcomes of Sleep Questionnaire (FOSQ), change in Epworth Sleepiness Scale (ESS), Clinical Global Impression Improvement (CGI-I), and therapy utilization metrics. With 80% statistical power and a 5% one-sided significance level, the study aims to reject the null hypothesis that the percentage of responders in evaluable subjects at Month 60 will be less than 50%. This study will continue to follow participants for up to 5 years, with endpoints assessed and reported yearly till the 60-month mark, and subjects will undergo biannual impedance checks to assess IPG function and battery status.

PAS Progress Reports must be submitted every six (6) months for the first year and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA. The Final PAS Report should be submitted no later than three (3) months after study completion (i.e., last subject's last follow-up date).

From the date of study protocol approval, you must meet the following timelines for New Enrollment Study (Post-Approval Study):

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months

- 100% of subjects enrolled within 24 months

In addition, you must submit separate periodic reports on the progress of New Enrollment Study (Post-Approval Study) as follows:

- PAS Progress Reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA.
- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports every 3 months in addition to your periodic (6-month) PAS Progress Reports, until FDA notifies you otherwise.
- Submit the Final PAS Report three (3) months from study completion (i.e., last subject's last follow-up date).

Each PAS report should be submitted to the address below identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement, including initiation, enrollment, and completion requirements 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).

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post-Approval Studies Program Database Webpage, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

In addition, the results from any post approval study should be included in the labeling as these data become available. Under 21 CFR 814.39, any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order" (<https://www.fda.gov/media/71327/download>).

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 Part 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 available at <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. Additional information about changes that may require a PMA supplement are provided in 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>.

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production and process controls (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 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 <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 Part 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 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 to the CDRH Portal and should reference the above PMA number to facilitate processing. For more information on the CDRH Portal, please visit <https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal>.

If you have any questions concerning this approval order, please contact Farid Yaghouby at 240-402-2520 or Farid.Yaghouby@fda.hhs.gov.

Sincerely,

James J. Lee, Ph.D.
Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health