



September 18, 2025

Medtronic Neuromodulation
Jennifer Bennett
Principal Regulatory Affairs Specialist
7000 Central Ave., N.E.
MS RCE 480
Minneapolis, Minnesota 55432

Re: P240011

Trade/Device Name: Medtronic Altaviva System

Product Code: QPT

Filed: April 4, 2024

Amended: April 23, 2024; April 23, 2024; April 24, 2024; April 25, 2024; June 03, 2025; July 28, 2025

Dear Jennifer Bennett:

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 Medtronic Altaviva System. This device is indicated for treatment of urge urinary incontinence in patients who failed or could not tolerate more conservative treatments. 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 and insofar as the sale and distribution of the device are restricted to physicians trained in placement of tibial neuromodulation devices. 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 at 18 months.

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.

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. 24-month Follow-up of the "Evaluation of Implantable Tibial Neuromodulation (TITAN 2) Pivotal Study"

This study was initiated prior to device approval and is a single-arm, multi-center clinical study. It was conducted at 25 sites and enrolled 188 subjects. One hundred and twenty six (126) subjects were implanted in this study. The 12-month outcomes from the study were used to support PMA approval. The 24-months follow-up data from this study must be submitted to assess the continued safety and effectiveness of the Altaviva System. You must report the following clinical outcomes for 24-months follow-up:

Effectiveness

- Primary Effectiveness Endpoint: Percentage of subjects who experience an improvement in urge urinary incontinence (UUI) episodes of at least 50% or greater from baseline (therapy responders)
- Change from baseline in quality of life as measured and assessed by the total overactive bladder (OAB)-q Health Related Quality of Life (HRQL) score
- Change from baseline in mean number of UUI episodes
- Percentage of subjects who experience an improvement in OAB-q HRQL of at least 10 points
- Subgroup analysis of the UUI responder rate for the patient population 65 and older

Safety

- Comprehensive summary of all adverse events (AEs) for the duration of study participation, including all device- or procedure-related AEs and device- or procedure-related serious adverse events
- Revision rates
- Explantation rates

Device Use

- Device parameters including but not limited to voltage, pulse width, frequency, and stimulation duration/day

This PAS Report should be submitted no later than two (2) months after the approval of this PMA.

2. Tibial Neuromodulation (TNM) Post Approval Study

The purpose of this new enrollment PAS is to assess the long-term safety and effectiveness of the Altaviva system for the treatment of UUI in patients through 5 years of follow-up. This is a prospective, multicenter, single-arm, open-label study. Subjects that have symptoms of UUI will be enrolled. The study will be conducted at approximately 30 institutions in the United States. Eligible subjects must sign a study-specific informed consent form (ICF). Subjects must complete an Enrollment/Baseline Visit, a Device Implant Visit, 1-month, 6-month, 12-month and annual follow-up visits thereafter post implant until the 60-month follow-up visit is complete.

Approximately 256 subjects will be enrolled in the study to achieve a minimum of 170 implanted subjects to account for about 33% attrition between enrollment and implant. At least 90 subjects must be followed to 60 months post implant. Additionally, a least 50% of enrolled subjects must be aged 65 years or older. To ensure that a minimum of 50% of enrolled subjects are aged 65 years or older, enrollment may be opened exclusively to individuals within this age group during the study if needed.

You must collect and report the following for this PAS:

- Primary Effectiveness Endpoint: UUI responder rate annually through 60 months after implant. A UUI responder is defined as having at least 50% improvement from baseline in daily UUI episodes.
- Additional Effectiveness Endpoints:
 - The following endpoints should be evaluated annually through 60 months:
 - Change from baseline in daily UUI episodes
 - UUI responder rate for subjects aged 65 and older
 - Patient reported impression of improvement as measured with the Patient Global Impression of Improvement (PGI-I) questionnaire
 - Device and system usage data (i.e., stimulation parameters, duration and frequency of stimulation for each subject)
- Safety Endpoints:
 - Procedure-, device-, and/or therapy-related adverse events through 60 months by reporting the number of events, and number and percentage of subjects with events.
 - Serious adverse events through 60 months by reporting the number of events, and number and percentage of subjects with events

You must collect and record all adverse events regardless of relatedness.

The primary analysis must be conducted on the Intention-to-Treat (ITT) population (all subjects who are implanted), with results based on the voiding diary data and summarized using descriptive statistics. Missing data must be addressed based on the underlying reason for missingness. Subjects with missing data due to lack of efficacy must be classified as treatment failures, while all other missing data must be managed using multiple imputation under a missing-at-random assumption.

Additionally, in the ITT analysis set, the sensitivity analysis must be conducted considering all missing data as treatment failures without imputation for each follow-up visit through 60-months. In the ITT population, the sensitivity analysis must be conducted considering subjects with increase in overactive bladder medication or the subjects receiving additional treatments during the study, as treatment failures without imputation for each follow-up visit through 60-months. Additionally, specific subgroup analysis must be conducted with the ITT population at each annual follow-up through month 60 on the primary effectiveness endpoint data on age, OAB medication use in subjects by age (older than 65) and sex.

The approved protocol is Version 8.0, submitted via email on September 16, 2025.

From the date of study protocol approval, you must meet the following timelines for The Tibial Neuromodulation (TNM) PAS:

- 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 The Tibial Neuromodulation (TNM) PAS 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production and process controls (21 CFR 820.30 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, 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 Nabamita Pal, PhD at Nabamita.Pal@fda.hhs.gov.

Sincerely,

Sharon Andrews
Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health