July 22, 2026

Advanced Bionics
℅ Rebecca Rice
Principal Regulatory Affairs Specialist
Advanced Bionics, LLC
28515 Westinghouse Pl.
Valencia, California 91355

Re: P960058/S167
Trade/Device Name: HiResolution™ Bionic Ear System
Product Code: MCM
Filed: January 29, 2025
Amended: April 23, 2026 (A001)

Dear Rebecca Rice:

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) supplement for the HiResolution™ Bionic Ear System to expand the indications for use to include individuals 5 years of age or older with profound hearing loss in one ear, also known as single-sided deafness (SSD)/asymmetric hearing loss (AHL), and normal hearing to mild to moderately severe hearing loss in the other ear. The device is indicated for:

The HiResolution™ Bionic Ear System is intended to restore a level of auditory sensation to individuals with severe-to-profound sensorineural hearing loss via electrical stimulation of the auditory nerve.

Bilateral Hearing Loss

Adults
18 years of age or older.

- Severe to-profound, bilateral sensorineural hearing loss (≥ 70 dB HL).
- Postlingual onset of severe or profound hearing loss.
- Limited benefit from appropriately fitted hearing aids, defined as scoring 50% or less on a test of open-set sentence recognition (HINT Sentences).

Children
12 months through 17 years of age.

- Profound, bilateral sensorineural deafness (≥ 90 dB HL).

- Use of appropriately fitted hearing aids for at least 6 months in children 2 through 17 years of age, or at least 3 months in children 12 through 23 months of age. The minimum duration of hearing aid use is waived if x-rays indicate ossification of the cochlea.
- Little or no benefit from appropriately fitted hearing aids. In younger children (< 4 years of age), lack of benefit is defined as a failure to reach developmentally appropriate auditory milestones (such as spontaneous response to name in quiet or to environmental sounds) measured using the Infant-Toddler Meaningful Auditory Integration Scale or Meaningful Auditory Integration Scale or ≤ 20% correct on a simple open-set word recognition test (Multisyllabic Lexical Neighborhood Test) administered using monitored live voice (70 dB SPL). In older children (≥ 4 years of age), lack of hearing aid benefit is defined as scoring ≤12% on a difficult open-set word recognition test (Phonetically Balanced-Kindergarten Test) or ≤ 30% on an open-set sentence test (Hearing In Noise Test for Children) administered using recorded materials in the soundfield (70 dB SPL).

Unilateral Hearing Loss
The HiResolution™ Bionic Ear System is indicated for individuals with unilateral hearing loss who meet the following criteria:

Asymmetric Hearing Loss (AHL)
Individuals with AHL are defined as those with a mild to moderately severe hearing loss in the better ear, i.e., a 4PTA of 31 to 65 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz, with a difference of at least 15 dB in the 4PTA between ears.

It is recommended that individuals with AHL have at least two (2) weeks experience wearing an appropriately fitted Contralateral Routing of Signal (CROS) system or suitable hearing device prior to cochlear implantation.

The ear to be implanted will be as follows:

Adults (18 years of age or older):
- Severe to profound sensorineural hearing loss (4PTA of 500, 1000, 2000, and 4000 Hz ≥ 80 dB HL)
- A score of ≤ 20% on a Consonant-Nucleus-Consonant (CNC) word test

Children (5 years through 17 years of age):
- Profound sensorineural hearing loss (4PTA of 500, 1000, 2000, and 4000 Hz ≥ 90 dB HL)
- Insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on a developmentally appropriate monosyllabic word list when tested in the ear to be implanted alone.

Single-Sided Deafness (SSD)
Individuals with SSD are defined as those with normal hearing or mild sensorineural hearing loss in the better ear (4PTA of ≤ 30 dB HL at 500, 1000, 2000, and 4000 Hz).

It is recommended that individuals with SSD have at least two (2) weeks experience wearing an appropriately fitted Contralateral Routing of Signal (CROS) system or suitable hearing device prior to cochlear implantation.

The ear to be implanted will be as follows:

Adults (18 years of age or older):

- Severe to profound sensorineural hearing loss (4PTA of 500, 1000, 2000, and 4000 Hz ≥ 80 dB HL)
- A score of ≤ 20% on a Consonant-Nucleus-Consonant (CNC) word test

Children (5 years through 17 years of age):

- Profound sensorineural hearing loss (4PTA of 500, 1000, 2000, and 4000 Hz ≥ 90 dB HL)
- Insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on a developmentally appropriate monosyllabic word list when tested in the ear to be implanted alone.

Based upon the information submitted, the PMA supplement 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.

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 CDRH Portal. 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 a PMA supplement that includes a complete protocol of your post-approval study described below. Your PMA supplement should be clearly labeled as a "PMA Post-Approval Study Protocol" as noted below and submitted to the CDRH Portal. 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. The Advanced Bionics New Enrollment Asymmetric Hearing Loss/Single-Sided Deafness (AHL/SSD) Study is a new enrollment post-approval study intended to assess the long-term safety and effectiveness of the HiResolution™ Bionic Ear System in treating children and adults with AHL/SSD.

   The study will be conducted as a prospective, non-controlled, non-randomized, multicenter study and will include 64 subjects at up to 12 sites. Among the 64 subjects, 44 subjects will be 18 years of age or older. Twelve subjects will be between 5 and 12 years of age and 8 subjects will be between 12 and 18 years old. The primary safety endpoint is the number and proportion of subjects experiencing device-related adverse events throughout the duration of the post-approval study. The effectiveness endpoints include the within-subject differences for Consonant-Nucleus-Consonant (CNC) word recognition in quiet from the unilateral, pre-operative, best-aided condition to the unilateral, 12-month, post-activation condition, and Bamford-Kowal-Bench Speech in Noise (BKB-SIN) sentences from the bilateral, pre-operative, best-aided condition to the bilateral, 12-month, post-activation condition for speech and noise presented in S_0N_{NH} (signal from front, noise to normal ear), S_0N_0 (signal and noise from front), and S_0N_{CI} (signal from front, noise to the CI ear) configurations. The stability of perceived hearing benefits over time will be assessed in adults by employing the Speech, Spatial, and Qualities (SSQ) questionnaire. For pediatric subjects, the SSQ-child and SSQ-parent will be administered. Subjects will be followed at 3 months, 6 months, 12 months, 24 months, and 36 months post-activation visits.

From the date of study protocol approval, you must meet the following timelines for the Prospective Evaluation of Outcomes with Advanced Bionics Cochlear Implants in Children and Adults with Asymmetric Hearing Loss or Single-Sided Deafness 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 the Prospective Evaluation of Outcomes with Advanced Bionics Cochlear Implants in Children and Adults with Asymmetric Hearing Loss or Single-Sided Deafness Study 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 CDRH Portal 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 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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485

clause 8.5.3 (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 (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Lindsay DeVries, Au.D., Ph.D. at 240-402-1462 or Lindsay.DeVries@fda.hhs.gov.

Sincerely,

SRINIVAS NANDKUMAR -S

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental and
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