



November 26, 2025

Med-el Corp.
% Elizabeth Gfoeller
Corporate Director, Regulatory Affairs
MED-EL Corporation
Furstenweg 77a
Innsbruck, 6020
Austria

Re: P000025/S134
Trade/Device Name: MED-EL Cochlear Implant System
Product Code: MCM
Filed: February 12, 2025
Amended: August 28, 2025

Dear Dr. Elizabeth Gfoeller:

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 MED-EL Cochlear Implant System for expanding the indication for use. The expanded device indications include children with bilateral hearing loss who meet the following criteria:

The MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with debilitating sensorineural hearing loss (SNHL) who obtain limited benefit from acoustic amplification in the ear(s) to be implanted and is indicated for the following pediatric populations:

Children aged 7 months to 17 years, 11 months must demonstrate a bilateral SNHL as follows.

- Children implanted at 7-11 months of age should demonstrate a profound SNHL, defined by a 3-frequency pure-tone average (PTA3) of ≥ 90 dB HL at 500, 1000, and 2000 Hz.
- Children implanted at 12-71 months of age should demonstrate a moderately-severe to profound SNHL in the low frequencies, defined by a $PTA3 \geq 55$ dB HL at 500, 1000, and 2000 Hz and a severe to profound SNHL in the high frequencies with thresholds not better than 70 dB HL at 2000-8000 Hz.
- Children implanted at 6 years to 17 years, 11 months of age should demonstrate a moderate to profound SNHL in the low frequencies, defined by a low-frequency PTA (LFPTA) >40 dB HL at 250, 500, and 1000 Hz with thresholds not better than 65 dB HL at 3000-8000 Hz.

- Children implanted at 7 months to 5 years, 11 months of age must also demonstrate insufficient functional access to sound with appropriately fitted amplification and aural habilitation. Children who lack the requisite language to complete word recognition testing should demonstrate either a lack of progress or plateau on an accepted scale of auditory skill development (e.g., LittlEARS Auditory Questionnaire (LEAQ), Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)). Children with the requisite language to complete word recognition testing should demonstrate a percent correct score $\leq 40\%$ on a developmentally appropriate test of word recognition (e.g., based on age, cognitive ability, language skills, and clinical judgement).
- Children implanted at 6 years to 17 years, 11 months of age should demonstrate limited benefit from hearing aids, defined by test scores of 50% correct or less in the ear to be implanted and 60% or less in the non-implant ear on recorded tests of monosyllabic word recognition (e.g., Consonant-Nucleus- Consonant [CNC] Words).
- Children implanted under 12 months of age should show repeatable behavioral test results that are consistent with objective/electrophysiological test results.
- MED-EL strongly recommends a hearing aid trial of at least 1-3 months for children without previous hearing aid experience. Risk of ossification or lack of aidable hearing may preclude a hearing aid trial.

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). 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 three years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

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 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 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 the PAS listed below.

The MED-EL Cochlear Implant Pediatric Post-Approval Study (PAS) combines an extended follow-up study and a new, prospectively designed, retrospective study to assess long-term safety and effectiveness of cochlear implantation in children aged 7 months to 18 years. The study will be conducted as a prospective/retrospective, non-controlled, non-randomized, multicenter study at 8 sites. Prospective evaluation for safety and effectiveness up to a minimum of 2 years post-implantation will be conducted among approximately 26 children implanted at ages 7-12 months who were enrolled in the prospective arm of the premarket, prospectively designed, prospective/retrospective study for the extended follow-up study. Retrospective evaluation for safety and effectiveness up to a minimum of 2 years post-implantation will be conducted among a minimum of 80 new subjects implanted at ages 12 months to 18 years (30 subjects implanted at ages 1-6 years and 50 subjects implanted at ages 6-18 years) for the new, prospectively designed, retrospective study. The primary safety endpoint is the number and proportion of subjects experiencing device-, procedure-, or otologic-related adverse events up to 24 months post-implantation. The effectiveness endpoints will include the within-subject differences in cochlear implant performance on age-appropriate speech perception from the pre-implantation baseline to the 24-month post-implantation condition.

From the date of study protocol approval, you must meet the following timelines for the PAS 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 PAS 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 complying with the PAS 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 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 Ting Zhang, Ph.D. at 301-796-1289 or Ting.Zhang@fda.hhs.gov.

Sincerely,

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health