Review Summary

May 19, 2026

Pharmaceuticals and Medical Devices Agency

The following are the summary of the review of the following medical device submitted for marketing approval conducted by the Pharmaceuticals and Medical Devices Agency (PMDA).

Classification	:	Medical Product 4, Orthopedic product
Term name	:	Auditory electrical stimulator
Brand name	:	1. Nucleus 8 Sound Processor 2. Cochlear Implant 6
Applicant	:	Nihon Cochlear Co., Ltd.
Date of application	:	May 28, 2025
Date of approval	:	February 3, 2026
Application classification	:	☐New medical device ☒Improved medical device (with clinical data) ☐Improved medical device (without clinical data)
New approval / Partial Change		☐New approval ☒Partial change
Review category	:	☐Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry ☐Cardiopulmonary Circulation ☐Dentistry and Oral Medicine ☐Gastroenterology, Genitourinary, and Reproductive Medicine ☒Ophthalmology and Otorhinolaryngology ☐Orthopedic and Plastic Surgery ☐Robotics, IoT, and other devices (not classified as other categories) ☐Program D1 ☐Program D2
Items warranting special mention	:	☐Designated as medical devices with high medical need ☐Designated as specific-usage medical device ☐Application in accordance with conditional early approval system for medical devices (Type 1)

☐Application in accordance with conditional early approval system for medical devices (Type 2: “Physical operation of items’ extrapolative and inclusive approval” (Phoenix))

☐Application in accordance with the notification on pre- and post-market rebalancing (☐1st step ☐2nd step)

☐Application in accordance with “Improvement design within approval for timely evaluation and notice” (IDATEN)

☐Designated as orphan medical device

☐Application in accordance with the 0929 notification

☐Other ( )

Expert Discussion : ☐Yes ☒No

1. Submitted data

(1) Background of the development

Nucleus 8 Sound Processor and Cochlear Implant 6 (hereinafter referred to as "the products") are Auditory electrical stimulator (Note: Auditory electrical stimulator is the term name) used in patients with bilateral severe hearing loss. This application is submitted to enable the product to be used in patients with Single-side severe hearing loss and Asymmetrical severe hearing loss.

(2) Non-clinical data

Nonclinical data of Nucleus 8 Sound Processor were omitted based on the identity with the approved product. The following nonclinical data of Cochlear Implant 6 were submitted.

- Data on conformity to usability engineering process: IEC 62366-1:2015 + A1:2020.

(3) Clinical data

The applicant submitted a clinical evaluation report consisting of the literature in overseas. The outline of the data is as follows.

The efficacy and safety of the products in patients with single-side severe hearing loss and asymmetrical severe hearing loss were evaluated in a literature survey (159 reports) on clinical use experience overseas.

In terms of efficacy, the products were applied to patients with single-side severe hearing loss and asymmetrical severe hearing loss and improved speech perception, sound localization, spatial hearing, speech understanding, hearing fatigue, and tinnitus under noise.

Regarding safety, no new risks specific to patients with single-side severe hearing loss and asymmetrical severe hearing loss, including effects on the good hearing ear, were reported, and were assessed as acceptable compared with conventional cochlear implants for patients with bilateral severe hearing loss despite known

risks, such as potential need for surgical bleeding, infection, or device removal.

2. Review Results

PMDA concluded that the application based on the clinical evaluation report is acceptable because the clinical efficacy caused by the intended physical effect of the product is considered to be publicly known in medical and pharmaceutical fields. As a result of the review of the submitted data, PMDA concluded that the product could be approved.

<Intended use>

It is used to restore sound perception by electrically stimulating the auditory nerve in patients with bilateral, single-side, or asymmetrical severe hearing loss who do not achieve adequate hearing aid effects.