Review Summary

July 23, 2026

Pharmaceuticals and Medical Devices Agency

The following is 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. SYNCHRONY 2 FLEX 2. SYNCHRONY 2 3. MED-EL Audio Processors SONNET 4. MED-EL Audio Processors RONDO
Applicant	:	MED-EL Elektro-Medizinische Gera(¨)te GmbH
Date of application	:	1. September 29, 2025 2. October 2, 2025 3. December 10, 2025 4. January 8, 2026
Date of approval	:	June 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

SYNCHRONY 2 FLEX, SYNCHRONY 2, MED-EL Audio Processors SONNET and MED-EL Audio Processors RONDO (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 SYNCHRONY 2 and MED-EL Audio Processors SONNET were omitted based on the identity with the approved product. The following nonclinical data of SYNCHRONY 2 FLEX and MED-EL Audio Processors RONDO 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 results of prospective clinical studies conducted in Japan using the advanced health care system and the overseas literature. The outline of the data is as follows (the clinical results section of the package insert is cited).

The efficacy and safety of the products in patients with single-side severe hearing loss and asymmetrical severe hearing loss were evaluated in the results of prospective clinical studies conducted in Japan using the advanced health care system and a literature survey (46 reports) on clinical use experience overseas.

<Summary of Reporting on Clinical Results of Advanced Medicine>

A prospective study of changes in speech discrimination, orientation, and free-field thresholds before and after SYNCHRONY wearing was performed in 38 patients using the advanced medical care system in Japan. As a result, improvement from preoperative was observed in all variables in 36 patients, excluding 2 patients who dropped out. In a safety review of 38 patients, only known adverse events in bilateral severe hearing loss were considered to be associated with the use of cochlear implants, and there was no indication of an increased significant risk associated with the use of the products in patients with single-side severe hearing loss and asymmetrical severe hearing loss.

<Outline of published papers>

The efficacy was improved in speech discrimination, sound localization, tinnitus and quality of life in patients with single-sided severe hearing loss and asymmetrical severe hearing loss. Regarding safety, the reported events were known to occur after cochlear implantation and there were no reports of new risks to patients with single-side severe hearing loss and asymmetrical severe hearing loss, including effects on the good ear.

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.

SYNCHRONY 2 FLEX

<Intended use>

- Electrically stimulate the auditory pathways of patients with bilateral severe hearing loss who do not have adequate hearing aid to restore some hearing.
- Electrical stimulation of the auditory pathway in patients with single-side or asymmetrical severe hearing loss who do not achieve adequate hearing aid effects to restore part of the hearing.
- Acoustic and electrical stimuli are applied to the auditory pathways of patients with high-pitched, low-pitched sensorineural deafness who are unable to achieve adequate hearing aid effects to restore part of the hearing.

SYNCHRONY 2

MED-EL Audio Processors SONNET

MED-EL Audio Processors RONDO

<Intended use>

- Electrically stimulate the auditory pathways of patients with bilateral severe hearing loss who do not have adequate hearing aid to restore some hearing.
- Electrical stimulation of the auditory pathway in patients with single-side or asymmetrical severe hearing loss who do not achieve adequate hearing aid effects to restore part of the hearing.