April 3, 2026

MED-EL Elektromedizinische Geräte GmbH
Vladislav Morozov
Advanced Specialist, Regulatory Affairs
Fürstenweg 77a
Innsbruck, Tirol 6020
Austria

Re: K260720
Trade/Device Name: mWING Stapes Prosthesis
Regulation Number: 21 CFR 874.3450
Regulation Name: Partial ossicular replacement prosthesis
Regulatory Class: Class II
Product Code: ETB
Dated: March 5, 2026
Received: March 5, 2026

Dear Vladislav Morozov:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOYCE C. LIN -S

for Shu-Chen Peng, Ph.D.
Assistant 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260720

Device Name
mWING Stapes Prosthesis

Indications for Use *(Describe)*

INTENDED USE:
The passive middle ear implant – stapesplasty prosthesis is intended to be used for replacement of the stapes arch or stapes arch and incus in case of a fixed stapes footplate. The stapesplasty prosthesis is implanted in the middle ear to restore sound transmission from the tympanic membrane to the oval window by replacing the ossicles partially. The stapesplasty prosthesis is a medical device for single use delivered in sterile condition.

INTENDED USER
The stapesplasty prosthesis is intended to be implanted by qualified ENT surgeons only, with adequate skills to perform otological surgeries. Replacement of the ossicular chain is a standard surgical procedure, no additional specific device training is mandatory or required for the safe and effective use.

TARGET PATIENT POPULATION
The target patient population for the passive middle ear implant are patients of all ages requiring reconstruction of the ossicular chain.

INDICATIONS:
The stapesplasty prosthesis is indicated to treat patients with:
- congenital or acquired defects of the stapes due to e.g., otosclerosis, congenital fixation of the stapes, traumatic injury, malformation of the ossicular chain or middle ear
- inadequate conductive hearing from previous stapes surgery

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY

MED-EL Elektromedizinische Geräte GmbH

[As Required by 21 CFR 807.92(c)]

1.0 Submitter [807.92(a)(1)]

Manufacturer:
MED-EL Elektromedizinische Geräte GmbH (hereafter MED-EL)
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Austria

Contact Person:
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Elizabeth Gfoeller
MED-EL Corporate Director, Regulatory Affairs
Phone: +43 577885614

Date the Summary was prepared: March 31, 2026.

2.0 Device Names [807.92(a)(2)]

Table 1 Device/Trade Names of MED-EL PMEI Stapesplasty Prostheses

Device/Trade Name	Device Classification Name	Classification	Product code	Regulation (CFR)
mWING Stapes Prosthesis	Partial ossicular replacement prosthesis.	Class II	ETB	874.3450

3.0 Predicate Devices [807.92(a)(3)]

Table 2 Predicate device manufactured by MED-EL

Predicate Device	
mAXIS Stapes Prosthesis	K241142

4.0 Description of the Devices [807.92(a)(4)]

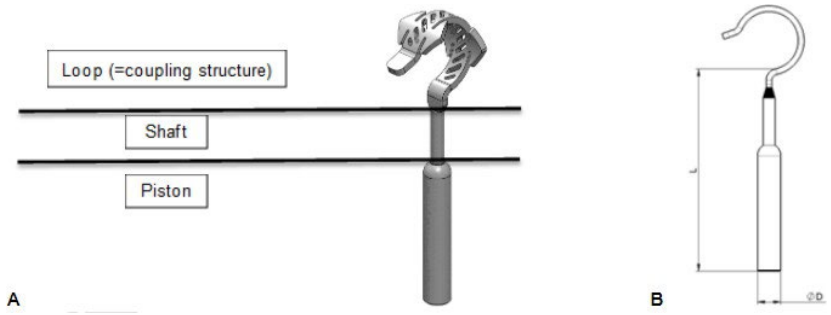

Figure 1: mWING Stapes Prosthesis.
A) Illustration of the structure of the prosthesis: Loop, Shaft and Piston. B) Schematic view: “L” functional length and “Ø D” diameter of the piston.

The mWING Stapes Prosthesis (Figure 1) is a partial ossicular replacement prosthesis which is used to restore the mechanical sound transmission to the oval window.

The mWING Stapes Prosthesis is made of medical grade titanium and consists of a piston, shaft and a loop-type coupling structure. The loop features a perforated, narrow loop-band with additional stabilizing wings that support controlled and stable manual crimping to the long process of the incus (or in case of a malleo-vestibulopexy directly to the malleus). The bendable shaft enables anatomical adaptation during implantation.

The mWING Stapes Prosthesis is offered in different fixed functional lengths (3.50 to 5.50 mm) & piston diameters (0.4 mm, 0.5 mm and 0.6 mm).

The functional length describes the distance between the lateral side of the incus or malleus (the ossicle the loop is coupled to) and the stapes footplate plus 0.5 mm insertion depth.

5.0 Statement of the Intended use [807.92(a)(5)]

The intended use and indications of the mWING Stapes Prosthesis and the predicate device are identical.

PMEI Stapesplasty Prostheses

Intended Use

The passive middle ear implant – stapesplasty prosthesis is intended to be used for replacement of the stapes arch or stapes arch and incus in case of a fixed stapes footplate. The stapesplasty prosthesis is implanted in the middle ear to restore sound transmission from the tympanic membrane to the oval window by replacing the ossicles partially. The stapesplasty prosthesis is a medical device for single use delivered in sterile condition.

Intended User

The stapesplasty prosthesis is intended to be implanted by qualified ENT surgeons only, with adequate skills to perform otological surgeries. Replacement of the ossicular chain is a standard surgical procedure, no additional specific device training is mandatory or required for the safe and effective use.

Target Patient Population

The target patient population for the passive middle ear implant are patients of all ages requiring reconstruction of the ossicular chain.

Indications:

The stapesplasty prosthesis is indicated to treat patients with:

- congenital or acquired defects of the stapes due to e.g., otosclerosis, congenital fixation of the stapes, traumatic injury, malformation of the ossicular chain or middle ear.
- inadequate conductive hearing from previous stapes surgery.

6.0 Comparison of Technological Characteristics with predicate devices [807.92(a)(6)]

Table 3 mWING Stapes Prosthesis. Substantial Equivalence Comparative Table of technological parameters/features and characteristics. n/a not applicable.

Parameters / Features / Characteristics	*SUBJECT DEVICE* **mWING Stapes Prosthesis (K260720)** MED-EL Elektromedizinische Geräte GmbH	*PREDICATE DEVICE* **mAXIS Stapes Prosthesis (K241142)** MED-EL Elektromedizinische Geräte GmbH
Intended Use and Indications for Use		
Intended Use	The passive middle ear implant – stapesplasty prosthesis is intended to be used for replacement of the stapes arch or stapes arch and incus in case of a fixed stapes footplate. The stapesplasty prosthesis is implanted in the middle ear to restore sound transmission from the tympanic membrane to the oval window by replacing the ossicles partially. The stapesplasty prosthesis is a medical device for single use delivered in sterile condition.	
Indications for Use	The stapesplasty prosthesis is indicated to treat patients with: - congenital or acquired defects of the stapes due to e.g., otosclerosis, congenital fixation of the stapes, traumatic injury, malformation of the ossicular chain or middle ear - inadequate conductive hearing from previous stapes surgery	
Target population	Patients of all ages	
Technological characteristics		
Design	 Piston stapes prosthesis with offset loop; perforated loop-band with **additional stabilizing wings**	 Piston stapes prosthesis with offset loop; broad and perforated loop-band
Loop Ø	1.00 mm	1.00 mm
Loop opening	0.85 mm	0.85 mm
Loop width	0.30 mm	0.50 mm
Shaft Ø	0.2 mm	0.2 mm
Method of Attachment	Manually, with crimping	
Number of sizes (length and diameter	27 (9 for each piston Ø)	

variants)	
Dimensions (functional lengths) of the length variants [mm]	3.5, 3.75, 4.0, 4.25, 4.5, 4.75, 5.0, 5.25, 5.5
Piston Ø variants [mm]	0.4 / 0.5 / 0.6
Materials in body contact	Titanium ASTM F67, medical grade
Biocompatibility	Yes (EN ISO 10993)
Surgical Tools	MED-EL does not offer any mandatory or optional surgical tools.
Packaging configuration	One (1) length/diameter-variant per package
Single Use	Yes
Sterile	Yes
MRI	MRI Conditional at 1.5, 3.0 and 7.0 T

6.1 Summary of technological differences

Comparing the subject device mWING Stapes Prosthesis and its predicate device mAXIS Stapes Prosthesis, the method of attachment, number of sizes (length and piston diameter variants), material in body contact, biocompatibility, surgical tools, packaging configuration and MRI compatibility are IDENTICAL.

The following features are considered EQUIVALENT: device design. The loop-band is narrower for the subject device which enables a softer crimping process; to still enable stable crimping mWING Stapes Prosthesis features additional stabilizing wings.

A risk-based assessment was conducted to assess whether the differences of the subject device mWING Stapes Prosthesis as compared to the predicate device mAXIS Stapes Prosthesis could significantly affect safety or effectiveness.

7.0 Non-clinical Testing [807.92(b)(1)]

Non-clinical testing was performed to support the substantial equivalence of the mWING Stapes Prosthesis to the predicate device. Because the subject device and predicate device share identical materials, manufacturing processes, sterilization method, and packaging, several data sets from the predicate device were leveraged. Only testing related to the design modifications required new evaluations.

Testing leveraged from the predicate device:
These evaluations were not repeated, because the subject device does not introduce new worst-case conditions and falls fully within the previously validated configurations:

- MRI Safety (ASTM F2119, F2052, F2182)
- Biocompatibility (EN ISO 10993, FDA guidance FDA-2013-D-0350)
- Shelf-Life and Packaging (EN ISO 11607)
- Sterilisation validation (EN ISO 11137-1, EN ISO 11137-2)

New testing performed for the subject device:
Because the only modification is the geometry of the loop band and the addition of stabilizing wings, specific testing was conducted to evaluate the impact of this design change:

- Usability Testing (IEC 62366-1) to confirm that ENT surgeons can safely manipulate, position, and crimp the modified loop. Usability testing confirmed the usefulness of the additional stabilizing wings.

- Mechanical and Functional Bench Testing to verify handling characteristics and device integrity.

This non-clinical testing demonstrated that the design modifications for the mWING Stapes Prosthesis is substantially equivalent to the predicate device, the mAXIS Stapes Prosthesis.

8.0 Substantial Equivalence Discussion

The subject device and the identified predicate device are largely identical (see Table 3). Thus, bench tests for MRI, biocompatibility, shelf-life, sterilization and packaging were leveraged from testing performed on the predicate device. The design change of adding stabilization wings and narrowing the loop band required usability testing with the subject device. The performed usability testing according to IEC 62366-1:2015 confirmed that the modified design can be safely and effectively handled by its intended users. In addition, mechanical and functional bench testing was performed on the subject device and confirmed that the modified design does not adversely affect safety or intended performance.

9.0 Conclusion [807.92(b)(3)]

The non-clinical testing demonstrates that the subject device, the mWING Stapes Prosthesis is substantially equivalent to the predicate device, mAXIS Stapes Prosthesis, to perform its intended use safely and effectively.