April 3, 2026

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

Re: K260718
Trade/Device Name: mGRIP Partial Prosthesis and mDISC Partial 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)*
K260718

Device Name
mGRIP Partial Prosthesis and mDISC Partial Prosthesis

Indications for Use *(Describe)*

INTENDED USE:
The passive middle ear implant – tympanoplasty partial prosthesis is intended to be used for replacement of components of the ossicular chain, if at least the stapes footplate is present and functional. The tympanoplasty partial 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 tympanoplasty prosthesis is a medical device for single use delivered in sterile condition.

INTENDED USER
The tympanoplasty 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 tympanoplasty prosthesis is indicated to treat patients with:
- congenital or acquired ossicular chain defects (e.g., chronic otitis media, traumatic injury, malformation, cholesteatoma)
- inadequate conductive hearing from previous middle ear surgery

The partial ossicular replacement prosthesis is indicated, if at least the stapes head and its stapes footplate are present and functional.

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.

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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 Tympanoplasty Partial Prostheses

Device/Trade Name	Device Classification Name	Classification	Product code	Regulation (CFR)
mGRIP Partial Prosthesis	Partial Ossicular replacement Prosthesis	Class II	ETB	874.3450
mDISC Partial Prosthesis				

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

Table 2 Predicate device manufactured by MED-EL

Predicate Device	
mXACT Partial Prosthesis	K241261

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

mGRIP Partial Prosthesis

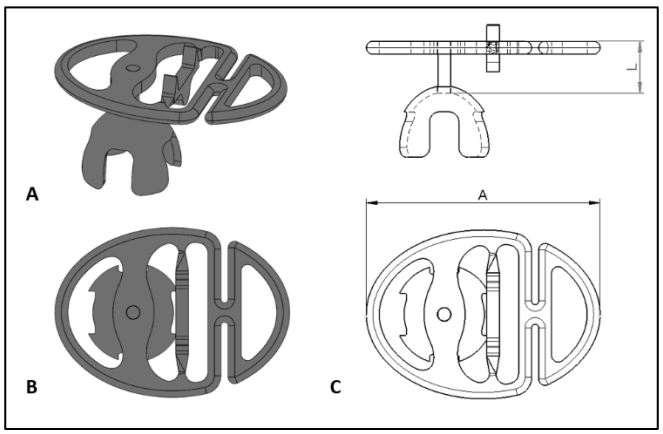

Figure 1: mGRIP Partial Prosthesis partial ossicular replacement prosthesis. A) 3D-view, B) Top-view, C) Schematic view: “L” functional length of the PORP prosthesis. “A” length of the headplate.

The mGRIP Partial Prosthesis (Figure 1) is a partial ossicular replacement prosthesis (PORP) which is used to bridge the gap between the tympanic membrane and the stapes head.

The mGRIP Partial Prosthesis is made of medical grade titanium and consists of a bell-shaped coupling structure, a bendable shaft, and a headplate with integrated “spikes”. The headplate offers a bending option to allow coupling to the malleus handle. The spikes are delivered prebent 90° towards the cartilage. The spikes stabilize the cartilage to the prosthesis which shall lower the risk of early postoperative prosthesis dislocation. The fenestrated headplate allows good intraoperative visibility to the surgical field.

The mGRIP Partial Prosthesis is available in different fixed functional lengths (L: 0.75 to 3.50 mm).

The functional length describes the distance between the tympanic membrane and the stapes head. The headplate length (A) corresponds to the oval headplate dimensions (3.6 × 2.6 mm).

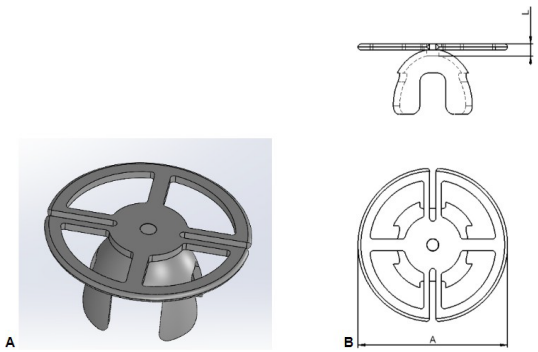

Figure 2: mDISC Partial Prosthesis partial ossicular replacement prosthesis.
A) 3D-view, B) Schematic view: “L” functional length of the PORP prosthesis. “A” length of the headplate.

The mDISC Partial Prosthesis (Figure 2) is a partial ossicular replacement prosthesis (PORP) which is used to bridge the gap between the tympanic membrane and the stapes head.

The mDISC Partial Prosthesis is made of medical grade titanium and consists of a bell-shaped coupling structure and a round headplate without a shaft. The shaftless design enables use in very small tympanic cavities where conventional prosthesis lengths are too long. The round headplate can be bent intraoperatively to support anatomical alignment.

The mDISC Partial Prosthesis is available as one functional length variant (L: 0.20 mm).

The functional length describes the distance between the tympanic membrane and the stapes head. The headplate length (A) corresponds to the round headplate diameter (Ø 2.6 mm).

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

The intended use and indications of the mGRIP Partial Prosthesis and mDISC Partial Prosthesis and the predicate device are identical.

PMEI Tympanoplasty Partial Prostheses

Intended Use

The passive middle ear implant – tympanoplasty partial prosthesis is intended to be used for replacement of components of the ossicular chain, if at least the stapes footplate is present and functional. The tympanoplasty 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 tympanoplasty prosthesis is a medical device for single use delivered in sterile condition.

Intended User

The tympanoplasty 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 tympanoplasty prosthesis is indicated to treat patients with:

- congenital or acquired ossicular chain defects (e.g., chronic otitis media, traumatic injury, malformation, cholesteatoma).
- inadequate conductive hearing from previous middle ear surgery.

The partial ossicular replacement prosthesis is indicated, if at least the stapes head and its stapes footplate are present and functional.

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

6.1 mGRIP Partial Prosthesis

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

Parameters / Features / Characteristics	*SUBJECT DEVICE* **mGRIP Partial Prosthesis (K260718)** MED-EL Elektromedizinische Geräte GmbH	*PREDICATE DEVICE* **mXACT Partial Prosthesis (K241261)** MED-EL Elektromedizinische Geräte GmbH
Intended Use and Indications for Use		
Intended Use	The passive middle ear implant – tympanoplasty partial prosthesis is intended to be used for replacement of components of the ossicular chain, if at least the stapes footplate is present and functional. The tympanoplasty 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 tympanoplasty prosthesis is a medical device for single use delivered in sterile condition.	
Indications for Use	The tympanoplasty prosthesis is indicated to treat patients with: - congenital or acquired ossicular chain defects (e.g., chronic otitis media, traumatic injury, malformation, cholesteatoma) - inadequate conductive hearing from previous middle ear surgery The partial ossicular replacement prosthesis is indicated, if at least the stapes head and its stapes footplate are present and functional.	
Target population	Patients of all ages	
Technological characteristics		
Design		
Headplate	Oval (3.6 x 2.6 mm), bendable	Oval (3.6 x 2.6 mm), bendable
Shaft	Ø 0.2 mm	Ø 0.2 mm
Coupling Structure	Bell	Bell
Additional features	headplate with integrated spikes	n/a
Method of Attachment	Bell-shaped coupling structure for the placement onto the stapes head	
Number of sizes (length variants)	10	

Dimensions (functional lengths) of the length variants [mm]	0.75, 1.0, 1.25, 1.5, 1.75, 2.0, 2.25, 2.5, 3.0, 3.5
Shaft Ø [mm]	0.2
Headplate dimensions	Ø 2.60 x 3.60 mm (oval and off-centric)
Materials in body contact	Medical grade titanium ASTM F67
Biocompatibility	Yes (EN ISO 10993)
Surgical Tools (mandatory)	n/a
Surgical Tools (optional)	Tympanoplasty Sizers for partial prostheses (Class I). Material: polypropylene
Packaging configuration	One (1) prosthesis per package
Single Use	Yes
Sterile	Yes
MRI	MRI Conditional at 1.5, 3.0 and 7.0 T

6.2 mDISC Partial Prosthesis

Table 4 mDISC Partial Prosthesis. Substantial Equivalence Comparative Table of technological parameters/features and characteristics. n/a not applicable.

Parameters / Features / Characteristics	*SUBJECT DEVICE* **mDISC Partial Prosthesis (K260718)** MED-EL Elektromedizinische Geräte GmbH	*PREDICATE DEVICE* **mXACT Partial Prosthesis (K241261)** MED-EL Elektromedizinische Geräte GmbH
Intended Use and Indications for Use		
Intended Use	The passive middle ear implant – tympanoplasty partial prosthesis is intended to be used for replacement of components of the ossicular chain, if at least the stapes footplate is present and functional. The tympanoplasty 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 tympanoplasty prosthesis is a medical device for single use delivered in sterile condition.	
Indications for Use	The tympanoplasty prosthesis is indicated to treat patients with: - congenital or acquired ossicular chain defects (e.g., chronic otitis media, traumatic injury, malformation, cholesteatoma) - inadequate conductive hearing from previous middle ear surgery The partial ossicular replacement prosthesis is indicated, if at least the stapes head and its stapes footplate are present and functional.	
Target population	Patients of all ages	
Technological characteristics		

Design Headplate Shaft Coupling Structure Additional features	 Round (Ø 2.6 mm), bendable no shaft Bell no shaft	 Oval (3.6 x 2.6 mm), bendable Ø 0.2 mm Bell n/a
Method of Attachment	Bell-shaped coupling structure for the placement onto the stapes head	
Number of sizes (length variants)	1	10
Dimensions (functional lengths) of the length variants [mm]	0.2	0.75, 1.0, 1.25, 1.5, 1.75, 2.0, 2.25, 2.5, 3.0, 3.5
Shaft Ø [mm]	no shaft	0.2
Headplate dimensions	Ø 2.60 (round and centric)	Ø 2.60 x 3.60 mm (oval and off-centric)
Materials in body contact	Medical grade titanium ASTM F67	
Biocompatibility	Yes (EN ISO 10993)	
Surgical Tools (mandatory)	n/a	
Surgical Tools (optional)	Tympanoplasty Sizers for partial prostheses (Class I). Material: polypropylene	
Packaging configuration	One (1) prosthesis per package	
Single Use	Yes	
Sterile	Yes	
MRI	MRI Conditional at 1.5, 3.0 and 7.0 T	

6.3 Summary of technological differences

Comparing the subject devices and the predicate device, the following parameters, features and characteristics were considered **IDENTICAL** or **EQUIVALENT** to the predicate device.

Parameters, features, characteristics	**mGRIP Partial Prosthesis** as compared to its predicate device (mXACT Partial Prosthesis)	**mDISC Partial Prosthesis** as compared to its predicate device (mXACT Partial Prosthesis)
Headplate Design	EQUIVALENT	EQUIVALENT
Shaft Design	IDENTICAL	EQUIVALENT
Coupling Structure	IDENTICAL	IDENTICAL
Additional features	EQUIVALENT	EQUIVALENT
Method of Attachment	IDENTICAL	IDENTICAL
Number of sizes (length variants)	IDENTICAL	EQUIVALENT
Shaft design	IDENTICAL	EQUIVALENT
Headplate dimensions	IDENTICAL	EQUIVALENT
Materials in body contact	IDENTICAL	IDENTICAL
Biocompatibility	IDENTICAL	IDENTICAL
Surgical Tools	IDENTICAL	IDENTICAL
Packaging configuration	IDENTICAL	IDENTICAL
Single Use	IDENTICAL	IDENTICAL
Sterile	IDENTICAL	IDENTICAL
MRI	IDENTICAL	IDENTICAL

A risk-based assessment was conducted to assess whether the differences of the subject devices mGRIP Partial Prosthesis and mDISC Partial Prosthesis as compared to the predicate device mXACT Partial 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 mGRIP Partial Prosthesis and mDISC Partial Prosthesis to the predicate device. Because the subject devices and the predicate device share identical materials, manufacturing processes, sterilization method, and packaging, several datasets 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 devices do not introduce new worst-case conditions and fall 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 devices:

mGRIP Partial Prosthesis
Because the only modification is the integration of spikes in the headplate, 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 the mGRIP Partial Prosthesis and place it in the foreseen middle ear structure. Usability testing confirmed the usefulness of the headplate spikes.

- Mechanical and Functional Bench Testing to verify handling characteristics and device integrity (increased lateral stability of a spike-headplate prosthesis as compared to a non-spike-headplate prosthesis was confirmed).

mDISC Partial Prosthesis
Because the only modification is that mDISC Partial Prosthesis has no shaft and that the headplate is round instead of oval, 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 the mDISC Partial Prosthesis and place it in the foreseen middle ear structure. Usability testing confirmed the usefulness of a shaftless prosthesis.

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

This non-clinical testing demonstrated that the design modifications for the mGRIP Partial Prosthesis and mDISC Partial Prosthesis are substantially equivalent to the predicate device, the mXACT Partial Prosthesis.

8.0 Substantial Equivalence Discussion

The subject devices and the identified predicate device are largely identical (see Table 3 and Table 4). Thus, bench tests for MRI, biocompatibility, shelf-life, sterilization and packaging were leveraged from testing performed on the predicate device. The design changes of adding spikes to the headplate for mGRIP Partial Prosthesis, or to have a shaftless prosthesis with a round headplate for mDISC Partial Prosthesis, required usability testing with the subject devices. 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. Additionally, bench testing confirmed the increased lateral stability of a spike-headplate prosthesis as compared to a non-spike-headplate prosthesis.

9.0 Conclusion [807.92(b)(3)]

The non-clinical testing demonstrates that the subject devices, the mGRIP Partial Prosthesis and mDISC Partial Prosthesis, are substantially equivalent to the predicate device, mXACT Partial Prosthesis to perform its intended use safely and effectively.