January 17, 2025

Med-El Elektromedizinische Geräte GmbH
Inés Román Santiago
Senior Regulatory Affairs
Fürstenweg 77a
Innsbruck, Tirol 6020
Austria

Re: K241142
Trade/Device Name: mAXIS Stapes Prosthesis, mLOOP Stapes Prosthesis, mZAM Stapes Prosthesis and mFIX Stapes Prosthesis
Regulation Number: 21 CFR 874.3450
Regulation Name: Partial Ossicular Replacement Prosthesis
Regulatory Class: Class II
Product Code: ETB
Dated: December 19, 2024
Received: December 19, 2024

Dear Inés Román Santiago:

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 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 (21 CFR 820.30 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 systems (QS) regulation (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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K241142

Device Name
mAXIS Stapes Prosthesis, mLOOP Stapes Prosthesis, mZAM Stapes Prosthesis and mFIX 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.

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510(k) SUMMARY of Safety and Effectiveness

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

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Date the Summary was prepared: 17th January 2025.

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

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

Device/Trade Name	Generic category & Medical Specialty	Classification	Product code	Regulation (CFR)
mAXIS Stapes Prosthesis	Middle ear, Prosthesis, **Partial** Ossicular Replacement Prostheses (Ear, Nose & Throat)	Class II	ETB	874.3450
mLOOP Stapes Prosthesis				
mZAM Stapes Prosthesis				
mFIX Stapes Prosthesis				

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

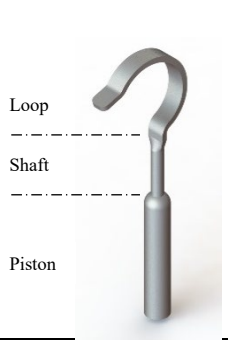
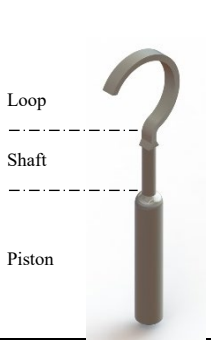
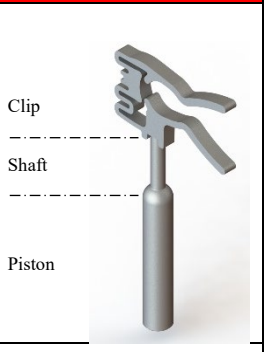
Table 2 Predicate devices manufactured by Heinz Kurz GmbH

MED-EL device	Primary Predicate Device A		Predicate Device B	
mAXIS Stapes Prosthesis	Detroit Piston	K130512	N/A	N/A
mLOOP Stapes Prosthesis			Kurz K-Piston	K002221
mZAM Stapes Prosthesis			Skarzynski Piston	K130512
mFIX Stapes Prosthesis			Clip Piston àWengen	K021479

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

The MED-EL "Passive Middle Ear Implants" (PMEIs) Stapesplasty Prostheses are partial ossicular replacement prostheses which restore the mechanical sound transmission to the oval window. A partial (stapedotomy) or total opening of the footplate (stapedectomy) is required. The distal end (=piston) of the device is placed into the opening of the inner ear. The other end of the prosthesis (=Loop or Clip) is coupled to the long process of the incus or to the handle of the malleus.
They are offered in different designs, functional lengths and/or piston diameters to allow the surgeon to have more flexibility in terms of selecting the correct prosthesis according to the individual patient´s anatomical needs, and the surgeon´s surgical preferences and proficiency.

Table 3 Description of the MED-EL PMEI Stapesplasty

Device/Trade Name	mAXIS	mLOOP	mZAM	mFIX
	Stapesplasty Prosthesis			
Design				
Coupling structure	Spiral-shaped loop for easier application			Clip for standardized coupling
	Loop band width = 0.5mm (broad & perforated loop)	Loop band width = 0.3mm	Loop band width = 0.20mm	Clip band width =0.2mm
Material	Medical grade titanium			
Method of Attachment	Manually, with crimping			Manually, with clipping
Sterile / Single-Use	Yes			

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

The intended use and indications of the MED-EL PMEI Stapesplasty Prostheses and of the predicate device(s) manufactured by Heinz Kurz GmbH are substantially equivalent.
Comparing the subject devices and the respective predicate devices, the same medical conditions or underlying pathologies can be treated, and the principal functionality of the devices is the same, hence no different questions of safety and effectiveness arise.

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:

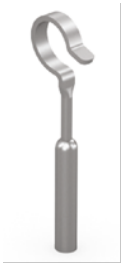
- congenital or acquired defects of the stapes due to e.g., otosclerosis, congenital fixation of the stapes, traumatic injury, malformation of the ossicular chain or middle ear.
- inadequate conductive hearing from previous stapes surgery.

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

The MED-EL PMEIs have the same technological characteristics (i.e. design, material, chemical composition, etc.) as the predicate devices identified in paragraph (a)(3). Hence, no difference in safety and effectiveness of the MED-EL PMEI Stapesplasty Prostheses as compared to the predicate device(s) from Heinz Kurz GmbH is expected. A summary of the technological characteristics is provided in the following table.

6.1 PMEI Stapesplasty Prostheses – Comparison with predicate devices

Table 4: PMEI Stapesplasty Prostheses - Comparison of Technical Characteristics

MED-EL Device / Predicate Device	"mAXIS Stapes Prosthesis"	**Predicate Device [A]** "Detroit Piston" (K130512)	"mLOOP Stapes Prosthesis"	**Predicate Device [B]** "K-Piston" (K002221)	"mZAM Stapes Prosthesis"	**Predicate Device [B]** "Skarzynski Piston" (K130512)	"mFIX Stapes Prosthesis"	**Predicate Device [B]** "Clip Piston àWengen" (K021479)
Design								
	Broad, perforated & spiral-shaped loop		Spiral-shaped loop		Narrow band & spiral-shaped loop		Clip-type coupling structure	
Attachment	Manually, with crimping						Manually, **without** crimping	
# of sizes	27	24	28		27	16	18	16
Piston Ø [mm]	0.4 / 0.5 / 0.6		0.4 / 0.6		0.4 / 0.5 / 0.6	0.4 / 0.6	0.4 / 0.6	
Functional lengths [mm]	3.5, 3.75, 4.0, 4.25, 4.5, 4.75, 5.0, **5.25**, 5.5	3.5, 3.75, 4.0, 4.25, 4.5, 4.75, 5.0, 5.5	3.5, 3.75, 4.0, 4.25, 4.5, 4.75, 5.0, 5.25, 5.5, 6.0, 7.0, 8.0, 9.0, 10.0		3.5, 3.75, 4.0, 4.25, 4.5, 4.75, 5.0, **5.25**, 5.5	3.5, 3.75, 4.0, 4.25, 4.5, 4.75, 5.0, 5.5	3.5, 3.75, 4.0, 4.25, 4.5, 4.75, 5.0, **5.25**, 5.5	3.5, 3.75, 4.0, 4.25, 4.5, 4.75, 5.0, 5.5
Loop width [mm]	0.50		0.30		0.20	0.25	0.20	0.25

Materials	Medical grade titanium ASTM F67	Medical grade titanium ASTM F136 (clip) and ASTM F67 (shaft, piston)	Medical grade titanium ASTM F67
Biocompatible	Yes (EN ISO 10993)		
Surgical Tools (mandatory)	N/A		
Surgical tools (optional)	MED-EL does not offer any optional surgical tool for the PMEI Stapesplasty Prosthesis. The manufacturer of the predicate device(s) offers the "KURZ-Meter" as an optional surgical tool.		
Packaging	One length/diameter-variant per package; Single-Use; Sterile		
MRI	MRI Conditional at 1.5, 3.0 and 7.0 T		

Comparing the MED-EL PMEI Stapesplasty Prostheses and their identified predicate device(s) manufactured by Heinz Kurz GmbH, the method of attachment, biocompatibility, packaging configuration and MRI compatibility are IDENTICAL.

The following features are considered EQUIVALENT: device design, number and dimensions of length/diameter variants, materials in body contact. As there is no difference in technological characteristics, there is no difference in safety and/or effectiveness.

There is just one difference: the surgical tools. For intraoperative measuring of the required prosthesis length, Heinz Kurz GmbH provides the KURZ-Meter however MED-EL does not provide such a tool due to other optional surgical tools are available on the market that can be used to determine the required prosthesis length to be used during a well-established stapes replacement surgical procedure. Thus, as there is no difference in technological characteristics, there is no difference in safety and effectiveness of the MED-EL PMEI Stapesplasty Prostheses compared to the predicate devices from Heinz Kurz GmbH is expected.

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

Non-clinical testing was conducted to assess the performance data for a determination of substantial equivalence.

The following tests were conducted:

- MRI environment according to ASTM F2119, F2052, F2182
  - MRI Conditional at 1.5T, 3.0T and 7.0T
- Biocompatibility according to EN ISO 10993
  - The performed evaluation provides objective evidence to support the conclusion that the devices can be considered biocompatible for their intended use.
- Shelf-Life testing according to EN ISO 11607
- Sterilization Validation according to EN ISO 11137-1, EN ISO 11137-2.
  - Gamma Sterilization with a confidence sterility assurance level of $<10^{6}$
- Packaging Validation according EN ISO 11607
- Mechanical & other testing

Safety and effectiveness have been demonstrated with non-clinical testing, concluding that the design and performance requirements are met.

8.0 Clinical Test [807.92(b)(2)]

The benefit for patients of the PMEI Stapesplasty Prostheses has been successfully demonstrated and the clinical outcomes of the MED-EL PMEI Stapesplasty Prostheses are comparable to the predicate devices as per the state of the art for these types of devices.

The goal of a stapes prosthesis is to close the postoperative pure tone average (PTA_4) air-bone gap (ABG) to within 20 dB, ideally to within 10 dB. According to the state of the art, as assessed in several systematic literature reviews and meta-analysis, more than 90 % of patients implanted with a stapes prosthesis achieve a postoperative PTA_4 ABG ≤20 dB. A variable fraction of stapes prosthesis implanted patients (41.0-87.2 %) even achieves a postoperative PTA_4 ABG to within 10 dB.

MED-EL conducted a large multicenter, retrospective, single-subjects repeated measures (each subject served as his or her own control) Post-Market Clinical Follow-Up (PMCF) investigation with the PMEI Stapesplasty Prosthesis in Europe:

- Audiological outcomes:
  - Number of patients: 168 (115 female, 53 male)
  - Age: mean 46.4 ± 12.9 years (range 12-70)
  - Implanted ear: 86 right, 82 left
  - Follow-up: median 49.5 days (mean 64.6 ± 61.4; range 7-470 days)
  - Prosthesis type: 88 mAXIS, 50 mLOOP, 11 mZAM, 19 mFIX
  - % patients with a postoperative PTA_4 ABG ≤20 dB: 91.7 %
  - % patients with a postoperative PTA_4 ABG ≤10 dB: 66.1 %
  - Mean BC-PTA_4 pre/post-surgery: 26.6 ± 10.3 dB HL / 23.9 ± 10.8 dB HL
  - BC-PTA_4 deterioration >10 dB HL: 9/168 patients = 5.4 % (range 11.3-21.3 dB HL)

- Adverse events:
  - Number of analyzed patients: 188 (127 female, 61 male)
  - Age: mean 47 ± 13 years (range 12-82)
  - Implanted ear: 98 right, 90 left
  - Follow-up: median 179.0 days (mean 246.4 ± 212.8; range 7-709 days)
  - Prosthesis type: 93 mAXIS, 64 mLOOP, 11 mZAM, 20 mFIX
  - Number of revision surgeries: 0 (2 recommended)
  - Number of device dislocations/extrusions: 0
  - Total 16 AEs in 13 patients: 7 Device unrelated AEs, 2 Medical related AEs, 2 Clinical/surgical related AEs, 5 AEs "unknown", 0 Follow-up AE

In the above mentioned PMCF investigation the safety and effectiveness of the PMEI Stapesplasty Prostheses was confirmed as demonstrated by postoperative PTA_4 ABG ≤20 dB rates and postoperative PTA_4 ABG ≤10 dB rates comparable to the state of the art, low rates of device dislocations/extrusions and revision surgeries, and overall stable bone conduction thresholds, an indicator that residual inner ear hearing is not compromised after implantation with an ossicular replacement prosthesis. Safety and effectiveness of the MED-EL PMEI Stapesplasty Prostheses are comparable to the current state of the art.

9.0 Conclusion [807.92(b)(3)]

The collective result of the non-clinical testing demonstrates that:

- the MED-EL PMEI Stapesplasty Prostheses meet the established specifications, the design and performance requirements to ensure safety and effectiveness according to the intended use.
- there is no difference in safety and/or effectiveness between MED-EL PMEI Stapesplasty Prostheses and the predicate devices manufactured by Heinz Kurz GmbH.

It can be concluded that the MED-EL PMEI Stapesplasty Prostheses are substantially equivalent to the predicate devices manufactured by Heinz Kurz GmbH.