January 17, 2025

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

Re: K241261
Trade/Device Name: mCLIP Partial Prosthesis, mCLIP ARC Partial Prosthesis, mXACT Partial Prosthesis and mXACT PRO Partial Prosthesis Kit
Regulation Number: 21 CFR 874.3450
Regulation Name: Partial Ossicular Replacement Prosthesis
Regulatory Class: Class II
Product Code: ETB
Dated: December 18, 2024
Received: December 18, 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K241261

Device Name
mCLIP Partial Prosthesis, mCLIP ARC Partial Prosthesis, mXACT Partial Prosthesis and mXACT PRO Partial Prosthesis Kit

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 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.

Tympanosplasty Sizers for partial prosthesis
(Note that the tympanosplasty Sizers are packaged together with the mXACT PRO Partial Prosthesis conforming the mXACT PRO Partial Prosthesis Kit).

INTENDED USE
The tympanoplasty Sizers are intended to be used during a partial ossicular replacement surgery to determine the required functional length of the MED-EL tympanoplasty prosthesis.

The tympanoplasty Sizers are optional, single-use surgical tools for intraoperative transient use only and delivered in sterile condition.

The Sizers for partial prosthesis are intended to intraoperatively determine the distance between the head of the stapes and the tympanic membrane, thereby determining the required functional length of the MED-EL tympanoplasty prosthesis.

INDICATIONS
The indications of the PMEI tympanoplasty partial prostheses apply.

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:
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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 PMEIs Tympanoplasty Partial Prostheses

Device/Trade Name	Generic category & Medical Specialty	Classification	Product code	Regulation (CFR)
mCLIP Partial Prosthesis	Middle ear, Prosthesis, **Partial** Ossicular Replacement Prostheses (Ear, Nose & Throat)	Class II	ETB	874.3450
mCLIP ARC Partial Prosthesis				
mXACT Partial Prosthesis				
mXACT PRO Partial Prosthesis Kit	Middle ear, Prosthesis, **Length -Adjustable and Partial** Ossicular Replacement Prostheses (Ear, Nose & Throat)			

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	
mXACT Partial Prosthesis	TTP-Tuebingen Type BELL Partial Prosthesis	K972492	N/A	N/A
mXACT PRO Partial Prosthesis Kit			TTP- VARIAC System Partial	K990923
mCLIP Partial Prosthesis			CLIP Partial Prosthesis Dresden Type	K013573
mCLIP ARC Partial Prosthesis			CliP Partial FlexiBAL	K013573

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

The MED-EL "Passive Middle Ear Implants" (PMEI) Tympanoplasty Partial Prostheses are partial ossicular replacement prostheses which restore the mechanical sound transmission to the oval window.
They are offered in different designs and fixed or adjustable functional length 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 Tympanoplasty Partial Prostheses

Device/Trade Name	mXACT Partial Prosthesis	mXACT PRO Partial Prosthesis Kit	mCLIP Partial Prosthesis	mCLIP ARC Partial Prosthesis
Design		mXACT PRO Partial Prosthesis:  + Sizers for partial prostheses: 		

<table>
<tr><td>System/Kit Components and Accessories</td><td>N/A</td><td><u>System/Kit content:</u>
1 mXACT PRO Partial Prosthesis + 5 Sizers for partial prostheses</td><td colspan="2">N/A</td></tr>
<tr><td>Coupling structure</td><td colspan="2">Round & “bell-shaped” for optimized stability on the stapes head</td><td colspan="2">Universal clip for standardized coupling on the stapes head</td></tr>
<tr><td rowspan="2">Headplate</td><td rowspan="2">Oval wih optional bending possibility</td><td>Oval & length adjustable (through snap-mechanism)</td><td rowspan="2">Round with optional bending possibility</td><td rowspan="2">Round with a ball-joint connection to the shaft.

The additional ball-joint allows the prosthesis to adapt itself to postoperative tympanic membrane movements (for example: caused by the healing process).</td></tr>
<tr><td>The surgeon can move the “shaft” inside the headplate to the desired functional length, afterwards the connection between headplate and shaft is fixed through the snap-mechanism inside the headplate. As a last step the overlapping titanium shaft of the prosthesis is cut-off with a scalpel.</td></tr>
<tr><td>Material</td><td>Medical grade titanium</td><td><u>mXACT PRO Partial Prosthesis:</u>
Medical grade titanium
<u>Sizer for partial prosthesis:</u> Polypropylene</td><td colspan="2">Medical grade titanium</td></tr>
<tr><td>Sterile / Single-Use</td><td colspan="4">Yes</td></tr>
</table>

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

The intended use and indications of the MED-EL PMEI Tympanoplasty Partial Prostheses and of the predicate devices 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 Tympanoplasty Partial Prostheses

<u>Intended Use</u>
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.

Tympanoplasty Sizers for partial prosthesis[1]

Intended Use

The tympanoplasty Sizers are intended to be used during a partial ossicular replacement surgery to determine the required functional length of the MED-EL tympanoplasty prosthesis. The Tympanoplasty Sizers are optional, single-use surgical tools for intraoperative transient use only and delivered in sterile condition.

The Sizers for partial prosthesis are intended to intraoperatively determine the distance between the head of the stapes and the tympanic membrane, thereby determining the required functional length of the MED-EL tympanoplasty prosthesis.

Indications

The indications of the PMEI tympanoplasty partial prostheses apply.

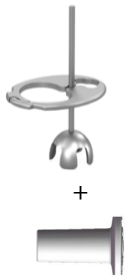
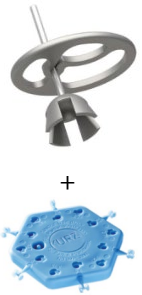
[1] Note that the "italic text" in this section shall be used if the tympanoplasty Sizers are packaged together with the mXACT PRO Partial Prosthesis conforming the mXACT PRO Partial Prosthesis Kit.

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 Tympanoplasty Partial Prostheses as compared to the predicate devices from Heinz Kurz GmbH is expected. A summary of the technological characteristics is provided in the following table.

6.1 PMEI Tympanoplasty PARTIAL Prostheses - Comparison with predicate devices

Table 4: PMEI Tympanoplasty Partial Prostheses - Comparison of Technical Characteristics

MED-EL Device / Predicate Device	"mXACT Partial Prosthesis"	Predicate Device [A] "TTP-Tuebingen Type BELL Partial Prosthesis" (K972492)	"mXACT PRO Partial Prosthesis Kit"	Predicate Device [B] "TTP-VARIAC System Partial" (K990923)	"mCLIP Partial Prosthesis"	Predicate Device [B] "CLIP Partial Prosthesis Dresden Type" (K013573)	"mCLIP ARC Partial Prosthesis"	Predicate Device [B] "Clip Partial FlexiBAL" (K013573)
Design								
	mXACT features a slit-headplate design for optional bending possibility	System/Kit content: 1x Partial ossicular replacement prosthesis 5 Sizers	1 Sizer Disc (including 6	mCLIP features a slit-headplate design for optional bending possibility and a clip with 8 "legs" instead of 7		Both devices have a ball-joint in the headplate. mCLIP ARC has a round and centric headplate		

				Sizers)				
			Design:					
			The mXACT headplate works with a snap-closing mechanism	TTP-VARIAC headplate with plastic deformation				
Attachment	Bell-shaped coupling structure for the placement onto the stapes head				Clip-shaped coupling structure for the placement onto the stapes head			
# of sizes	10	8	1 length adjustable partial prosthesis		10	8	10	8
			5 Sizers	1 Sizer Disc containing 6 Sizers				
Functional lengths [mm]	0.75, 1.00, 1.25, 1.50, 1.75, 2.00, 2.25, 2.50, **3.00, 3.50**	0.75, 1.00, 1.25, 1.50, 1.75, 2.00, 2.25, 2.50 **(*)**	length adjustable partial prosthesis can be adjusted to a functional length from 0.75 to 3.50		0.75, 1.00, 1.25, 1.50, 1.75, 2.00, 2.25, 2.50, **3.00, 3.50**	0.75, 1.00, 1.25, 1.50, 1.75, 2.00, 2.25, 2.50 **(*)**	0.75, 1.00, 1.25, 1.50, 1.75, 2.00, 2.25, 2.50, **3.00, 3.50**	0.75, 1.00, 1.25, 1.50, 1.75, 2.00, 2.25, 2.50 **(*)**
			Sizers functional length:					
			1.0, 1.5, 2.0, 2.5, 3.5	1.0, 1.5, 2.0, 2.5, 3.0, 3.5				
Shaft Ø [mm]	0.20							
Headplate dimensions [mm]	Ø2.60 x 3.60 (oval and off-centric)				Ø2.60 (round and centric)		Ø2.60 (round and centric)	Ø2.60 x 3.60 (oval and off-centric)
Materials	Medical grade titanium ASTM F67		Medical grade titanium ASTM F67 (bell and shaft) & ASTMF136 (headplate);	Medical grade titanium ASTM F67			Medical grade titanium ASTM F67, except the micro-ball which can be out of ASTMF67 or ISO 5832-2;	Medical grade titanium ASTM F67
Biocompatible	Yes (EN ISO 10993)							
Surgical Tools	N/A			Titanium Micro	N/A			

(mandatory)				Closing Forceps & Cutting Forceps				
Surgical Tools (optional)	Tympanoplasty Sizers for partial prostheses	AC^{Sizer} Disc Partial. Malleus Handle. Cavity Bending pliers.	Tympanoplasty Sizers for partial prostheses (included in the Kit)	AC^{Sizer} Disc Partial (included in the sales package). KURZ Titanium Tweezers. Micro Scissors	Tympanoplasty Sizers for partial prostheses	AC^{Sizer} Disc Partial	Tympanoplasty Sizers for partial prostheses	AC^{Sizer} Disc Partial
Packaging	One length variant per package; Single-Use; Sterile		One length variable partial ossicular replacement prosthesis + 5 Sizers for partial prostheses. Single-Use; Sterile		One length variant per package; Single-Use; Sterile			
MRI	MRI Conditional at 1.5, 3.0 and 7.0 T							

***** The predicate device uses a different type of length dimensioning, MED-EL directly specifies the functional length of the device (functional length is the distance between stapes head and the tympanic membrane), whereas for the predicate device the overall length is specified as part of the mentioned 510k. According to the homepage of the predicate device (see https://www.kurzmed.com/), the overall length of each variant is the functional length plus 1mm.

Comparing the MED-EL PMEI Tympanoplasty Partial Prostheses and their identified predicate devices manufactured by Heinz Kurz GmbH, the, biocompatibility, packaging configuration and MRI compatibility are IDENTICAL.

The following features are considered EQUIVALENT: device design, number and dimensions of length variants, headplate design, 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.
Sizers that can be used optionally to intraoperatively determine the required length of the prosthesis to be used are available for both, the subject devices as well as for the identified predicate devices.
The MED-EL tympanoplasty Sizers are either available separately (Class I) or packaged together with the mXACT PRO Partial Prosthesis conforming the mXACT PRO Partial Prosthesis Kit. Nevertheless, for the predicate devices, also additional optional tools (Malleus Handle Cavity Bending pliers, KURZ Titanium Tweezers, and Micro Scissors) are provided. Importantly, to adjust the prosthesis length, the TTP-VARIAC System Partial (Heinz Kurz GmbH) requires the surgeon to use special surgical tools for closing the headplate, instead, the headplate of the MED-EL mXACT PRO Partial Prosthesis can be closed with e.g. standard delicate tweezers. As this is considered an improvement, no difference in safety and effectiveness is expected. The safety and effectiveness of the closing mechanism of the MED-EL mXACT PRO Partial Prosthesis headplate was confirmed in non-clinical testing.

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

The goal of ossicular replacement prosthesis is to close the postoperative pure tone average (PTA_4) air-bone gap (ABG) to within 20 dB. According to the state of the art, as assessed in several systematic literature reviews and meta-analysis, 62.5-71.3 % of patients implanted with a partial prosthesis, achieve a postoperative PTA_4 ABG ≤20 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 Tympanoplasty Partial Prostheses in Europe:

- Audiological outcomes:
  - Number of patients: 186 (89 female, 97 male)
  - Age: mean 43.9 ± 18.6 years (range 5-81)
  - Implanted ear: 95 right, 91 left
  - Follow-up: median 70.0 days (mean 78.4 ± 55.3; range 3-302 days)
  - Prosthesis type: 48 mXACT Partial, 15 mXACT PRO Partial, 68 mCLIP Partial, 55 mCLIP ARC Partial
  - % patients with a postoperative PTA_4 ABG ≤20 dB: 72 %
  - Mean BC-PTA_4 pre/post-surgery: 19.8 ± 12.2 dB HL / 17.9 ± 12.2 dB HL
  - BC-PTA_4 deterioration >10 dB HL: 6/186 patients = 3.2 % (range 11.3-23.5 dB HL)
- Adverse events:
  - Number of analyzed patients: 202 (98 female, 104 male)

- Age: mean 44.5 ± 18.7 years (range 5-84)
- Implanted ear: 107 right, 95 left
- Follow-up: median 275.0 days (mean 284.0 ± 176.9; range 0-666 days)
- Prosthesis type: 52 mXACT Partial, 16 mXACT PRO Partial, 72 mCLIP Partial, 62 mCLIP ARC Partial
- Number of (recommended) revision surgeries: 5
- Number of (potential) device dislocations/extrusions: 3
- Total 34 AEs in 21 patients: 7 Device unrelated AEs, 4 Medical related AEs, 15 Clinical/surgical related AEs, 8 AEs "unknown", 2 Follow-up AE

In the above mentioned PMCF investigation the safety and effectiveness of the PMEI Tympanoplasty Partial Prostheses was confirmed as demonstrated by postoperative PTA_4 ABG ≤20 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 Tympanoplasty Partial Prostheses are comparable to the current state of the art.

9.0 Conclusion [807.92(b)(3)]

The results of the non-clinical testing demonstrate that:

- the MED-EL PMEI Tympanoplasty Partial 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 Tympanoplasty Partial Prostheses and the predicate devices manufactured by Heinz Kurz GmbH.

It can be concluded that the PMEI Tympanoplasty Partial Prostheses are substantially equivalent to the predicate devices manufactured by Heinz Kurz GmbH.