



January 17, 2025

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

Re: K241269

Trade/Device Name: mXACT Total Prosthesis Offcenter, mXACT Total Prosthesis Center and
mXACT PRO Total Prosthesis Kit

Regulation Number: 21 CFR 874.3495

Regulation Name: Total Ossicular Replacement Prosthesis

Regulatory Class: Class II

Product Code: ETA

Dated: December 16, 2024

Received: December 16, 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

510(k) Number (if known)
K241269

Device Name

mXACT Total Prosthesis Offcenter, mXACT Total Prosthesis Center and mXACT PRO Total Prosthesis Kit

Indications for Use (Describe)

INTENDED USE:

The passive middle ear implant – tympanoplasty total 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 total prosthesis is implanted in the middle ear to restore sound transmission from the tympanic membrane to the oval window by replacing the ossicles totally. 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 total ossicular replacement prosthesis is indicated, if at least the stapes footplate is present and functional.

Tympanoplasty Sizers for total prosthesis

(Note that the tympanoplasty Sizers are packaged together with the mXACT PRO Total Prosthesis conforming the mXACT PRO Total Prosthesis Kit).

INTENDED USE

The tympanoplasty Sizers are intended to be used during a total 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 total prosthesis are intended to intraoperatively determine the distance between the footplate 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 total 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 Total Prostheses

Device/Trade Name	Generic category & Medical Specialty	Classification	Product code	Regulation (CFR)
mXACT Total Prosthesis Offcenter	Middle ear, Prosthesis, Total Ossicular Replacement Prostheses (Ear, Nose & Throat)	Class II	ETA	874.3495
mXACT Total Prosthesis Center				
mXACT PRO Total Prosthesis Kit	Middle ear, Prosthesis, Length -Adjustable and Total 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 Total Prosthesis Offcenter	TTP- Tuebingen Type AERIAL Total Prosthesis	K972585	N/A	N/A
mXACT Total Prosthesis Center			Duesseldorf Type AERIAL Total Prosthesis	K972585
mXACT PRO Total Prosthesis Kit			TTP- VARIAC System Total	K990923

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

The MED-EL "Passive Middle Ear Implants" (PMEIs) Tympanoplasty Total Prostheses are total 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 Total Prostheses

Device/Trade Name	mXACT Total Prosthesis Offcenter	mXACT Total Prosthesis Center	mXACT PRO Total Prosthesis Kit
Design			<u>mXACT PRO Total Prosthesis:</u>  + <u>Sizers for total prostheses:</u> 

System/Kit Components and Accessories	N/A		<u>System/Kit content:</u> 1 mXACT PRO Total Prosthesis + 7 Sizers for total prostheses
Coupling structure	Cannulated "stem" for optimized stability on the stapes footplate		
Headplate	Oval with optional bending possibility	Round with optional bending possibility	Oval & length adjustable (through snap-mechanism)
			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.
Material	Medical grade titanium		<u>mXACT PRO Total Prosthesis:</u> Medical grade titanium <u>Sizer for total prosthesis:</u> Polypropylene
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 Tympanoplasty Total 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 Total Prostheses

Intended Use

The passive middle ear implant – tympanoplasty total 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 total prosthesis is implanted in the middle ear to restore sound transmission from the tympanic membrane to the oval window by replacing the ossicles totally. 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 total ossicular replacement prosthesis is indicated, if at least the stapes footplate is present and functional.

Tympanoplasty Sizers for total prosthesis¹

Intended Use

The tympanoplasty Sizers are intended to be used during a total 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 total prosthesis are intended to intraoperatively determine the distance between the footplate 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 total 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 Total Prosthesis conforming the mXACT PRO Total Prosthesis Kit.

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

The MED-EL Passive Middle Ear Implants (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 Total 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 Tympanoplasty TOTAL Prostheses - Comparison with predicate devices

Table 4 PMEI Tympanoplasty Total Prostheses - Comparison of Technical Characteristics

MED-EL Device / Predicate Device	"mXACT Total Prosthesis Offcenter"	Predicate Device [A] "TTP-Tuebingen Type AERIAL Total Prosthesis" (K972585)	"mXACT Total Prosthesis Center"	Predicate Device [B] "Duesseldorf Type AERIAL Total Prosthesis (K972585)"	"mXACT PRO Total Prosthesis Kit"	Predicate Device [B] "TTP-VARIAC System Total (K990923)"
Design						
mXACT features a slit-headplate design for optional bending possibility					System/Kit content: 1x Total ossicular replacement prosthesis	

					7 Sizers	1 Sizer Disc (including 8 Sizers)
					<u>Design:</u> The mXACT headplate works with a snap-closing mechanism	
Attachment	Cannulated distal footing to be placed centrally on the stapes footplate					
# of sizes	13	14	13	14	1 length adjustable total prosthesis	
					7 Sizers	1 Sizer Disc containing 8 Sizers
Functional lengths [mm]	3.0, 3.25, 3.5, 3.75, 4.0, 4.25, 4.5, 4.75, 5.0, 5.5, 6.0, 6.5, 7.0	3.0, 3.25, 3.5, 3.75, 4.0, 4.25, 4.5, 4.75, 5.0, 5.25 , 5.5, 6.0, 6.5, 7.0	3.0, 3.25, 3.5, 3.75, 4.0, 4.25, 4.5, 4.75, 5.0, 5.5, 6.0, 6.5, 7.0	3.0, 3.25, 3.5, 3.75, 4.0, 4.25, 4.5, 4.75, 5.0, 5.25 , 5.5, 6.0, 6.5, 7.0	Length adjustable total prosthesis can be adjusted to a functional length from 3.00 to 7.00	
					Sizers functional length:	
					3.0, 3.5, 4.0, 4.5, 5.0, 6.0, 7.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 7.0
Shaft Ø [mm]	Staged diameter: 0.2 / 0.25	0.2	Staged diameter: 0.2 / 0.25	0.2	0.20	
Headplate dimensions [mm]	Ø2.60 x 3.60 (oval and off-centric)		Ø2.60 x 3.60 (oval and centric)		Ø2.60 x 3.60 (oval and off-centric)	
Materials	Medical grade titanium ASTM F67				Medical grade titanium ASTM F67 (stem and shaft) & ASTM F136 (headplate);	Medical grade titanium ASTM F67
Biocompatible	Yes (EN ISO 10993)					
Surgical Tools (mandatory)	n/a					Titanium Micro Closing Forceps & Cutting Forceps
Surgical Tools (optional)	Tympanoplasty Sizers for total prostheses	AC ^{Sizer} Disc Total. Malleus Handle Cavity Bending pliers. Cartilage Punch.	Tympanoplasty Sizers for total prostheses	AC ^{Sizer} Disc Total. Malleus Handle Cavity Bending pliers. Cartilage Punch.	Tympanoplasty Sizers for total prostheses (included in the Kit)	AC ^{Sizer} Disc Total (included in the Kit). KURZ Titanium Tweezers Micro Scissors.



Packaging	One length variant per package; Single-Use; Sterile	One length variable total ossicular replacement prosthesis + 7 Sizers for total prostheses. Single-Use; Sterile
MRI	MRI Conditional at 1.5, 3.0 and 7.0 T	

Comparing the MED-EL PMEI Tympanoplasty Total 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 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 Total Prosthesis conforming the mXACT PRO Total Prosthesis Kit. Nevertheless, for the predicate devices, also additional optional tools (Cartilage Punch, Malleus Handle Cavity Bending pliers, KURZ Titanium Tweezers, and Micro Scissors) are provided. Importantly, to adjust the prosthesis length, the TTP-VARIAC System Total (Heinz Kurz GmbH) requires the surgeon to use special surgical tools for closing the headplate, instead, the headplate of the MED-EL mXACT PRO Total 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 Total 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 Total Prostheses has been successfully demonstrated and the clinical outcomes of the MED-EL PMEI Tympanoplasty Total 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 (PTA₄) 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, 48.3-57.4 % of patients implanted with a total prosthesis achieve a postoperative PTA₄ 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 Total Prostheses in Europe:

- Audiological outcomes:
 - Number of patients: 92 (47 female, 45 male)
 - Age: mean 40.3 ± 18.7 years (range 5-84)
 - Implanted ear: 48 right, 44 left
 - Follow-up: median 88.5 days (mean 88.3 ± 57.9 ; range 0-286 days)
 - Prosthesis type: 50 mXACT Total Offcenter, 22 mXACT Total Center, 20 mXACT PRO Total
 - % patients with a postoperative PTA₄ ABG ≤ 20 dB: 53.3 %
 - Mean BC-PTA₄ pre/post-surgery: 19.6 ± 11.3 dB HL / 17.5 ± 10.3 dB HL
 - BC-PTA₄ deterioration >10 dB HL: 1/92 patients = 1.1 % (11.3 dB HL)
- Adverse events:
 - Number of analyzed patients: 102 (52 female, 50 male)
 - Age: mean 40.5 ± 18.8 years (range 5-84)

- Implanted ear: 54 right, 48 left
- Follow-up: median 121.0 days (mean 219.7 ± 183.0; range 19-621 days)
- Prosthesis type: 57 mXACT Total Offcenter, 25 mXACT Total Center, 20 mXACT PRO Total
- Number of (recommended) revision surgeries: 3
- Number of (potential) device dislocations/extrusions: 1
- Total 4 AEs in 4 patients: 2 Medical related AEs, 2 Clinical/surgical related AEs

In the above mentioned PMCF investigation, the safety and effectiveness of the PMEI Tympanoplasty Total Prostheses was confirmed as demonstrated by postoperative PTA4 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 Total 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 Total 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 Total 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.