July 10, 2024

Oticon Medical AB
Pernilla Gustafsson
Head of Homologation
Datavagen 37 B
Askim, 436 32
Sweden

Re: K240614
Trade/Device Name: Sentio Ti Implant Kit; Sentio 1 Mini; Genie Medical BAHS
Regulation Number: 21 CFR 874.3340
Regulation Name: Active Implantable Bone Conduction Hearing System
Regulatory Class: Class II
Product Code: PFO
Dated: June 10, 2024
Received: June 10, 2024

Dear Pernilla Gustafsson:

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.

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

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.

Submission Number *(if known)*

K240614

Device Name

Sentio Ti Implant Kit;
Sentio 1 Mini;
Genie Medical BAHS

Indications for Use *(Describe)*

The Sentio Ti implant, in combination with Sentio 1 Mini, is indicated for the following patients:

• Patients with conductive or mixed hearing losses, who can still benefit from amplification of the sound. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2 and 3 kHz) of the indicated ear should be better than or equal to 45 dB HL.
• Patients having a symmetrically conductive or mixed hearing loss are candidates for a bilateral fitting. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2 and 3 kHz, or less than 15 dB at individual frequencies.
• Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single sided deafness or "SSD"). The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should then be better than or equal to 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).
• Patients who are indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.
• Prior to receiving the device, it is recommended that an individual has experience with appropriately fitted air conduction or bone conduction hearing aids.
• Patients 12 years of age or older.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) summary

A. Submitter Information

Submitted by:	Oticon Medical AB Datavägen 37B SE 436 32 Askim Sweden
Submission Contact Person:	Pernilla Gustafsson
Phone:	+46 (0)701436994
Email:	pegt@oticonmedical.com

B. Date prepared 2024-03-04

C. Device Information

Common Name:	Sentio Active Implantable Bone Conduction Hearing System
Device trade/proprietary name:	Sentio Ti Implant Kit Sentio 1 Mini Genie Medical BAHS
Classification Name:	Active implantable bone conduction hearing system
Classification Regulation:	21 CFR 874.3340
Device Classification:	Class II
Device Panel:	Ear, nose and throat
Device Product Code:	PFO
510(k) Number:	K240614

D.1 Predicate device

Common Name:	Bonebridge System
Device trade/proprietary name:	BCI 601 Implant kit BCI 602 Implant Kit Samba Audio Processor
Classification Name:	Active implantable bone conduction hearing system
Classification Regulation:	21 CFR 874.3340
Device Classification:	Class II
Device Panel:	Ear, nose and throat
Device Product Code:	PFO

De Novo Number: DEN170009

D.2 Reference device

Common Name:	Ponto
Device trade/proprietary name:	Ponto 5 SuperPower
Classification Name:	Bone conduction hearing aid
Classification Regulation:	21 CFR, 874.3302
Device Classification:	Class II
Device Panel:	Ear, nose and throat
Device Product Code:	LXB
510(k) Number:	K213733

E. Reason for the 510(k) Submission:

This is a new device submission for a pre-market notification 510(k).

F. Device Description

The Sentio system is an osseointegrating, transcutaneous active bone conduction hearing system that uses the body's natural ability to transfer sound through bone conduction, thus offering improvement of hearing for patients with conductive or mixed hearing loss whether unilaterally or bilaterally fitted, or for those with single sided deafness. A bone conduction system transmits sound directly to the cochlea independently of the function of the ear canal and middle ear.

The Sentio system primarily consists of a sound processor (Sentio 1 Mini) and an implant (Sentio Ti Implant). The two components are kept in place in relation to each other by means of a magnetic retention system. The sound is picked up by the microphones in the external sound processor, processed and transmitted by a transmission coil using a radio frequency (RF) link through the intact skin to an implant placed in the temporal and mastoid bone area. The receiver coil of the implant receives the signal that is converted into mechanical energy (vibrations) by the transducer. The vibrations are conveyed from the bottom of the transducer to the skull and thereafter by means of bone conduction to the cochlea. In the cochlea the vibrations are converted to signals that are transmitted to the brain through the auditory nerve.

The Sentio system is intended for improvement of hearing for patients with conductive or mixed hearing losses up to 45 dB BC. The implant has been tested and verified to allow for larger mixed hearing losses, up to an anticipated 65 dB BC.

G. Intended Use / Indications for Use

The Sentio Ti implant, in combination with Sentio 1 Mini, is indicated for the following patients:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of the sound. The pure tone average (PTA) bone conduction (BC)

threshold (measured at 0.5, 1, 2 and 3 kHz) of the indicated ear should be better than or equal to 45 dB HL.

- Patients having a symmetrically conductive or mixed hearing loss are candidates for a bilateral fitting. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2 and 3 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single sided deafness or "SSD"). The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should then be better than or equal to 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).
- Patients who are indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.
- Prior to receiving the device, it is recommended that an individual has experience with appropriately fitted air conduction or bone conduction hearing aids.
- Patients 12 years of age or older.

H. Substantial Equivalence Comparison

Assessment of substantial equivalence to the predicate devices MED-EL Bonebridge system (DEN 170009, with further features developed with the K183373, K191457 and K200504). And comparison to reference device Oticon Medical Ponto 5 SuperPower (K213733) sound processor.

The tables below summarize the substantial equivalence and reference device comparison on system (**table 1, page 4-5**) and component level; implant, (**table 2, page 6-7)** and sound processor (**table 3, page 8-9**). A comparison on the surgery implantation procedures of the two systems is summarized in **table 4, page 10**.

Table 1 summarizes the substantial equivalence comparison on system.

	Sentio System	Bonebridge System (predicate)	Substantial equivalence (Yes/No)
Intended use	The Sentio system is intended for improvement of hearing for patients with conductive or mixed hearing losses, whether unilaterally or bilaterally fitted, or for those with single sided deafness.	The Bonebridge is intended to improve hearing for patients with conductive or mixed hearing losses, bilateral fitting, and single-sided deafness.	Yes, difference in wording is not significant
Indications for use	• Patients with conductive or mixed hearing losses, who can still benefit from amplification of the sound. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2 and 3 kHz) of the indicated ear should be better than or equal to 45 dB HL. • Patients having a symmetrically conductive or mixed hearing loss are candidates for a bilateral fitting. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2 and 3 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., SSD). The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should then be better than or equal to 20 dB HL (measured at 0.5, 1, 2 and 3 kHz). • Patients who are indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS. • Prior to receiving the device, it is recommended that an individual has experience with appropriately fitted air conduction or bone conduction hearing aids. • Patients 12 years of age or older.	• Patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL. • Bilateral fitting of the Bonebridge is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies. • Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single-sided deafness or "SSD"). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz). • The Bonebridge for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS. • Prior to receiving the device, it is recommended that an individual have experience with appropriately fit air conduction or bone conduction hearing aids. • Patients 12 years of age or older.	Yes, difference in wording is not significant
Contraindications	• Known chronic or non-revisable vestibular or balance disorder. • Known abnormally progressive hearing loss.	• Chronic or non-revisable vestibular or balance disorders. • Abnormally progressive hearing loss.	Yes Patients already implanted with, or to be implanted

<table>
<tr><th></th><th>Sentio System</th><th>Bonebridge System (predicate)</th><th>Substantial equivalence (Yes/No)</th></tr>
<tr><td></td><td>• Evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment.
• Skin or scalp conditions that may preclude attachment of the sound processor or that may interfere with the use of the sound processor.
• Patients already implanted with, or to be implanted with, programmable CSF shunts.</td><td>• Evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment.
• Skin or scalp conditions that may preclude attachment of the audio processor or that may interfere with the use of the audio processor.
• Skull size or abnormality that would preclude appropriate placement of the BONEBRIDGE implant as determined by CT scan.</td><td>with, programmable CSF shunts are contraindicated for Sentio since verification has not been done.
For Sentio, pre-operative CT scan is typically not necessary for patients with normal anatomy, as evaluated in a clinical study.</td></tr>
<tr><td>Design</td><td>Active implantable bone conduction hearing system:
Transcutaneous implant which, in use together with an external sound processor that is held in place on the patient's head by magnetic attraction between the implant and the sound processor, uses the body’s natural ability to transfer sound through bone conduction.</td><td>Active implantable bone conduction hearing system:
Transcutaneous implant which, in use together with an external sound processor that is held in place on the patient's head by magnetic attraction between the implant and the sound processor, uses the body’s natural ability to transfer sound through bone conduction.</td><td>Yes</td></tr>
<tr><td>Anatomical site</td><td>Surgically implanted in the temporal and mastoid bone area.</td><td>Surgically implanted into the temporal bone.</td><td>Yes, the difference in wording does not have clinical significance as the mastoid is part of the temporal bone.</td></tr>
<tr><td>Intended environment</td><td><u>Implant:</u>
- Home care
- Professional Healthcare Facility
- Magnetic Resonance (MR) Environment

<u>Sound Processor:</u>
- Home care
- Professional Healthcare Facility</td><td><u>Implant:</u>
- Home care
- Professional Healthcare Facility
- Magnetic Resonance (MR) Environment

<u>Sound Processor:</u>
- Home care
- Professional Healthcare Facility</td><td>Yes</td></tr>
<tr><td>Transmission scheme</td><td>The difference between force output level at coupling distances of 9 mm and 3 mm is ≤ 5 dB</td><td>The difference between force output level at coupling distances of 7 mm and 4 mm is ≤ 4 dB</td><td>Yes, difference is not clinically significant.</td></tr>
<tr><td>System Force Output</td><td><table><tr><th>Frequency [Hz]</th><th>MPO [dB µ N]</th></tr><tr><td>500</td><td>90</td></tr><tr><td>1000</td><td>112</td></tr><tr><td>2000</td><td>96</td></tr><tr><td>4000</td><td>90</td></tr><tr><td>Peak</td><td>112</td></tr></table></td><td><table><tr><th>Frequency [Hz]</th><th>MPO [dB µ N]</th></tr><tr><td>500</td><td>90</td></tr><tr><td>1000</td><td>102</td></tr><tr><td>2000</td><td>96</td></tr><tr><td>4000</td><td>90</td></tr><tr><td>Peak</td><td>113</td></tr></table></td><td>Yes.
The choice of resonance frequency will affect the overall curve, but have outsized effect on specific frequencies. The resonance frequency is slightly lower for</td></tr>
</table>

	Sentio System	Bonebridge System (predicate)	Substantial equivalence (Yes/No)
			the predicate device compared to Sentio, and therefore has an outsized effect on the 1000Hz value. When taking the peak output into account we conclude that the overall difference in MFO is not clinically significant.

Table 1. Substantial Equivalence Comparison – System

Table 2 summarizes the substantial equivalence comparison for the Sentio Ti Implant.

	Sentio Ti Implant	Bonebridge BCI Implant (predicate)		Substantial equivalence (Yes/No)
Material	Titanium Silicone	Titanium Silicone		Yes
Biocompatibility	The Sentio Ti Implant is implanted in and above the mastoid bone and as such, is a device in permanent tissue/bone contact. Biocompatible. Materials in contact with tissue: - Implant: Titanium grade 2 and 5, medical grade silicone elastomer - Screws: Titanium Ti6Al4V	The BCI is implanted in and above the mastoid bone and as such, is a device in permanent tissue/bone contact. Biocompatible. Materials in contact with tissue: - Implant: Titanium grade 5, medical grade silicone elastomer - Screws: Titanium alloy Ti6Al7Nb		Yes
Compatibility with the environment and other devices	Diagnostic ultrasound X-Ray and CT Radiation therapy and PET MRI 1.5T Conditional	Diagnostic ultrasound X-Ray and CT Radiation therapy and PET MRI 1.5T Conditional		Yes
Sterility	EtO sterilization: Sentio Ti Implant Steam: Surgical templates	EtO sterilization		Yes, the Sentio surgical templates has a material and component characterization that doesn't require EtO, hence a different sterilization method (steam) is used.
Dimensions	Length: 60 mm Width: 30 mm Thickness: 4 mm	<u>BCI model 601</u> Length: 69 mm Width: 28,6 mm Thickness: 4,5 mm	<u>BCI model 602</u> Length: 64.3 mm Width: 28,2 mm Thickness: 4,4 mm	Yes, the footprint of Sentio Ti is smaller, a less deep recess is needed.
MRI	Magnet rotatable: No	Magnet rotatable: Yes		Yes, both systems meet the same safety standards and are MR Conditional at 1.5 T with their respective scanner settings.
	Magnet removable: No	Magnet removable: No		
	Magnet polarization: Axial	Magnet polarization: Diametric		
	Head bandaging requirement: No	Head bandaging requirement: No		
	Patient position: Supine position, centered in the MRI scanner.	Patient position: No restrictions		
	Temperature rise: Less than 2°C	Temperature rise: Less than 4°C		
	Permitted static magnetic field strength: 1.5 T	Permitted static magnetic field strength: 1.5 T		

	Sentio Ti Implant	Bonebridge BCI Implant (predicate)	Substantial equivalence (Yes/No)
	Maximum spatial field gradient: 20 T/m [2,000 G/cm]	Maximum spatial field gradient: Up to including 3000 Gauss/cm (30 T/m)	
	Maximum permitted whole-body averaged specific absorption rate (SAR) [W/kg]: 2 W/kg (normal operating mode)	Maximum permitted whole-body averaged specific absorption rate (SAR) [W/kg]: <4 W/kg (first level operating mode)	
	Maximum permitted head averaged SAR [W/kg]: 3.2 W/kg (Normal operating mode)	Maximum permitted head averaged SAR [W/kg]: <3.2 W/kg (Normal and first-level Operating Mode)	
	Scan duration: 15 min continuous scanning	Scan duration: 15 min continuous scanning	
	RF transmit coil type: Whole body transmit coil	RF transmit coil type: No restrictions	
	Scanner type: Cylindrical-bore	Scanner type: No restrictions	
	Magnetic field (B0) orientation: Horizontal	Magnetic field (B0) orientation: No restrictions	
	Maximum gradient slew rate per axis [T/m/s]: 200 T/m/s	Maximum gradient slew rate per axis [T/m/s]: No restrictions	
	A fixation band is applied across the transducer and two self-drilling, osseointegrating screws are inserted in the bone.	The implant is fixated with self-drilling screws into the bone. One screw is placed in each anchor hole of the BC-FMT.	
Fixation	A fixation band is applied across the transducer and two self-drilling, osseointegrating screws are inserted in the bone.	The implant is fixated with self-drilling screws into the bone. One screw is placed in each anchor hole of the BC-FMT.	Yes, the Sentio Ti Implant design offers flexibility in placement of the fixation whereas in Bonebridge the position of the screws are fixed as the fixation device is integrated with the transducer part of the implant.

Table 3 Comparison for the Sentio 1 Mini sound processor and SAMBA 2 Sound Processor (predicate).

	Sentio 1 Mini	Ponto 5 SuperPower (reference)	SAMBA 2 Sound Processor (predicate)	Substantial equivalence (Yes/No)
Dimensions	Length: 39 mm Width: 30 mm Thickness: 9 mm	Length: 31 mm Width: 21 mm Thickness: 15 mm	Length: 35 mm Width: 30 mm Thickness: 10 mm	Yes
Weight	8.6 g (incl. battery and magnet)	20.3 g (w/o battery)	< 9 g (incl. battery and magnet)	Yes
Battery	675 Zink-Air	675P Zink-Air	675 Zink-Air	Yes
Battery lifetime	>16 hours (avg. 61 hours, dependent on the usage of the sound processor)	>16 hours (dependent on the usage of the sound processor)	>16 hours (dependent on the usage of the sound processor)	Yes
Battery safety	Tamper-resistant battery drawer Tool for opening required		N/A	Yes, added safety feature to Ponto and Sentio sound processors
Magnet properties	6 magnet strengths	N/A	5 magnet strengths	Yes, difference is not clinically significant
Magnet safety	Tool for removing required	N/A	Tool for removing required	Yes
MRI	MR Unsafe	MR Unsafe	MR Unsafe	Yes
Variants	One variant Left or right assigned during fitting		Left and right variants	Yes, provides flexibility for clinician
Microphones	Dual directional microphones (various options)		Dual directional microphones (various options)	Yes
Sound processing features	64 processing channels Speech and noise management Directional microphones Wind noise management Feedback management		16 processing channels Speech and noise management Directional microphones Wind noise management	Yes
Frequency range	200-9500 Hz		250-8000 Hz	Yes, adds broader band width
Wireless features	Receiver and transmitter, 2.4 GHz, Bluetooth Low Energy		Receiver and transmitter, 3.28 MHz, NFMI (near field magnetic induction), Modulation type: FM *Note: Bluetooth available through compatibility with Siemens miniTek*	Yes, difference is not clinically significant
Accessories	Fixation option: Line a clip to be attached to sound processor and e.g., clothes.		Fixation option: Line a clip to be attached to sound processor and e.g., clothes.	Yes

	Sentio 1 Mini	Ponto 5 SuperPower (reference)	SAMBA 2 Sound Processor (predicate)	Substantial equivalence (Yes/No)
	Various cover colours and skins for personalization		Various cover colours and skins for personalization	
Compatibility with wireless accessories	Compatible wireless Oticon A/S/SBO Hearing A/S accessories: • Remote control 3.0 • ConnectClip • TV Adapter 3.0 • EduMic • Oticon Companion app *(Note: Companion app is a combination of the ON app and the RemoteCare app, previously cleared in K213733)*		SAMBA Remote control Siemens miniTek	Yes
Fitting software	Genie Medical BAHS		SYMFIT 8.0	Yes
Fitting options	Cabled fitting Wireless fitting Remote fitting		Cabled fitting	Yes, additional wireless and remote fitting are available with Sentio 1 Mini.

Table 3. Substantial Equivalence Comparison – Sound Processors

Table 4 compares the surgery implantation procedures of the two systems

	Sentio Ti Implant	Bonebridge Implant	Substantial equivalence (Yes/No)
Pre-operative planning	Pre-operative CT scan is typically not necessary for patients with normal anatomy. Pre-operative CT scan is recommended for patients where thin bone isexpected including: • Patients who have had previous surgery in the area of the implant site, and/or congenital craniofacial or auricular anomalies where a hypoplasia of the mastoidal anatomy might be present, e.g., congenital aural atresia, hemifacial microsomia/Goldenhar syndrome, Treacher Collin like syndromes and Branchio-Oto-Renal (BOR) syndrome. • Patients under the age of 18.	A CT scan is evaluated to determine where to place the BC-FMT (transducer) and the screws.	Yes, for Sentio, pre-operative CT scan is typically not necessary for patients with normal anatomy, as evaluated in a clinical study.
Implant positioning	A template is used to outline the position of the implant on the skin	A template is used to outline the position of the implant on the skin.	Yes
Incision	An incision is made.	An incision is made.	Yes
Preparation of the bone bed for the transducer	The site for the transducer is marked on the bone with the aid of a template. A standard otologic drill bit is used to createa bone bed, the transducer needs to be recessed by 3 mm.	The site for the transducer is marked on the bone with the aid of a template. A standard otologic drill bit is used to create a bone bed, the transducer needs to be recessed by 8.7 mm.	Yes, a less deep recess in the bone is needed for Sentio (3mm vs 8.75mm)
Preparation of pocket for the receiver coil	A periosteal pocket is prepared	A periosteal pocket is prepared	Yes
Implant installation	The receiver coil is inserted into thesubperiosteal pocket and the transducer is placed in the recess.	The receiver coil is inserted into the subperiosteal pocket and the transducer is placed in the recess.	Yes
Fixation	The fixation band is applied across the transducer and two self-drilling, osseointegrating screws are inserted in the bone	The implant is fixated with self-drilling screws into the bone. One screw is placed in each anchor hole of the BC-FMT and are secured tightly.	Yes, the Sentio Ti Implant design offers flexibility and in placement of the fixation whereas in Bonebridge the position of the screws are fixed as the fixation device is integrated with the transducer part of the implant.
Closure and dressing	The surgical wound is closed and a suitable dressing applied.	The surgical wound is closed and a suitable dressing applied.	Yes

Table 4. Comparison of Bonebridge and Sentio Surgery Implantation Procedure

I. Substantial Equivalence Conclusion

As the predicate MED-EL Bonebridge system (composed of Bonebridge BCI implants and SAMBA sound processors, DEN 170009, with further features developed with the K183373, K191457 and K200504), the Sentio system is an active implantable bone conduction hearing system, where the implant and the sound processor are kept in place in relation to each other by means of a magnetic retention system.

The Sentio system has the same principle of operation and the same source of energy as the predicate Bonebridge system; The Sentio 1 Mini sound processor incorporates an amplitude modulated signal on a carrier frequency of 120kHz in order to communicate with the Sentio Ti implant, in the same manner as the predicate system. The receiver coil of both the predicate implant and the Sentio Ti implant receives the carrier signal from the sound processors, and the signal is converted into mechanical energy (vibrations). For the Sentio system, vibrations are transferred from the bottom of the implant vibrator to the skull bone, whilst for the predicate Bonebridge implant, vibrations are transferred to the skull bone through the fixation screws. This minor difference does not affect the performance of the Sentio Ti Implant versus its predicate. The Sentio Ti Implant is installed in the temporal and mastoid bone area which is in the same anatomical position as the predicate Bonebridge implant. However, the implants differ in dimensions where the footprint of Sentio Ti is smaller and a less deep recess in the skull bone is needed for Sentio (maximum 3mm vs 8.75mm for the predicate implant).

Both the predicate and the Sentio Ti Implant are fixated in the bone with osseointegrating titanium alloy screws. In contrast to the predicate device, where the fixation is integrated with the transducer part of the implant, a fixation band is applied across the transducer of the Sentio Ti Implant. This offers flexibility in placement and allows for anatomical differences.

The Sentio 1 Mini sound processor also compares to predicate Oticon Medical Ponto 5 SuperPower (K213733) sound processor, which includes the same sound processing platform and wireless technology, enabling the same sound processing features and compatibility options. As the reference device, the Sentio 1 Mini incorporates wireless 2.4 GHz Bluetooth® Low Energy connectivity, side-neutral design, a LED status indicator, a tamper resistant battery drawer and user control of listening volume and program change.

Sentio 1 Mini sound processors are individually adjusted to the patient audiogram and needs by the Hearing Care professional using the Genie Medical BAHS fitting software, where Genie Medical BAHS 2023.1 uses the same functionality and features as Genie Medical BAHS 2022.1, previously cleared in K213733. The sound processors are connected either via cable to Hi-Pro2 or ExpressLink (wired fitting equipment) or wireless using Noahlink (wireless fitting equipment) or the Oticon Companion app (remote fitting equipment). The Oticon Companion app is a combination of the ON app and the RemoteCare app, previously cleared in K213733

J. Summary of Non-Clinical Performance

Electroacoustic verification of the Sentio system is conducted including tests for maximum force output, frequency range, peak output vibratory force level, and total harmonic distortion.

Performance of the Sentio Ti Implant and Sentio 1 Mini Sound Processor is evaluated for environmental impact relating to temperature, humidity and atmospheric pressure as applicable to their intended use environment. For the sound processors, additional noise floor testing and software verification has been performed and verified.

Mechanical integrity testing is performed to evaluate resistance of the Sentio Ti Implant to mechanical impact due to fatigue, damage/breakage or loss of hermeticity and skull impact. The reliability testing is performed in consistency with the expected implant lifetime (10 years).

The Sentio system has been confirmed to not emit excessive amounts of electromagnetic energy (EMC emissions) and to operate as intended without performance degradation or generation of hazardous sound or heat in the presence of an electromagnetic disturbance (EMC immunity) and electromagnetic discharge (ESD).

The Sentio Ti Implant is confirmed to resist unique medical emitters; electrocautery, therapeutic ionizing radiation, diagnostic levels of ultrasonic energy and diagnostic ionizing radiation and is MR Conditional at 1.5T.

The Sentio Ti implant include significant engineering improvements for MRI safety compared to implants with a traditional implant design. It consists of a non-removable retention magnet placed in a casing, connected to the transducer casing using a titanium reinforcement and covered with a hardened silicone overlay.

The result of the design is an improved pressure distribution across the entire antenna surface, avoiding pressure hotspots exceeding the directionally adapted pressure pain thresholds (PPTs) with a safety margin. The stress on the skin is minimized to a level far below the thresholds for the tissue preventing periosteum weakening and avoiding any mal effects on the skin flap. Apart from preventing magnet displacement/flipping, device migration, and dislodgement, these engineering improvements also minimize device flexure and displacement, compared to “traditional” magnet designs using soft silicone.

Sentio Ti has undergone extensive testing to ensure MRI safety for the Sentio Ti MR conditional labeling. In summary the Sentio Ti Implant reduces the pressure by 5x than traditional magnets without bandage and has a pressure pain perception safety factor of 16x based on bench tests, computer modeling, and pressure pain thresholds. The Sentio Ti can withstand 10 MR scans without damage.

The Sentio 1 Mini sound processor is a non-sterile component and does not require sterilization, nor does it have a restricted shelf-life. The Sentio Ti Implant Kit (composed of Sentio Ti Implant and Sentio Surgical Template Kit) is a sterile device for single use and is not intended to be end user sterilized nor is it intended for re-use. Shelf-life for the Sentio Ti Implant Kit is 3 years.

The Sentio system components and materials in direct and/or indirect tissue/skin contact are evaluated and tested for biocompatibility according to the requirements of ISO 10993 series.

K. Summary of Non-Clinical and Clinical Performance

Clinical data has been collected on the Sentio system in five clinical studies (see Table 1), whereof one pivotal study including 51 patients with the final design of the system (Sentio Ti implant and Sentio 1 Mini). In total, more than 113 years of accumulated patient user time have been studied with the first version of the Sentio implant (design iteration I1) and more than 47 years of accumulated patient user time have been studied with the final design of the system (Sentio Ti implant and Sentio 1 Mini).

The data consistently demonstrates that the system is safe and perform as intended. The small size and flexible implant position enables implantation without pre-operative CT scan in adult patients. Stable performance is seen across studies with improved ability to hear sounds and

improved speech intelligibility which also is reflected in higher quality of life scores reported after treatment. Performance results are in line with similar devices and other available treatment options for patients with conductive or mixed hearing loss, or single sided deafness. There are also good indications that performance results are stable over time (≥5 years) as reported for the first version of the Sentio implant (design iteration I1).

There are no indications that the Sentio system would impose new risks compared to similar devices that have been on the market for several years.

Long term safety and performance has been demonstrated for the first versions of Sentio implant. In addition, patients in study BC101 using the final design of the system (Sentio Ti implant and Sentio 1 Mini), have currently reported use of the device for more than 6 months (n = 29) and 12 months (n = 16), respectively. Long-term safety and performance are also supported by data on similar devices.

The available clinical data is deemed applicable also to the indicated age group 12-18 years. The mode of action, bone conduction, is independent on age as confirmed by data from other bone conduction devices. Considering available data on bone volume in the area of interest and the bone volume needed for implantation, it is estimated that children can be safely implanted. As a precaution, pre-operative imaging is recommended for the pediatric population to ensure that sufficient bone thickness is available. The risk of migration of the implant is deemed negligible and there is no risk of damaging the residual hearing or vital structures.In summary, the overall risk-benefit assessment concludes that the expected benefits with the Sentio system, used as intended, outweigh the potential risks and that the Sentio system compares favorably to similar devices and other available treatment options for patients with conductive or mixed hearing loss, or single sided deafness.

Study	Study design	Aim	Device	Patient group	Number of patients	Status
O1	Prospective, multi-center 1-year FU	Safety & performance	Implant: I1 Sound processor: SP1	Patient group 1	16	Completed
	Prospective, single-center, 3- and 5-year FU	Long term safety & performance			13	Completed
C58	Prospective, single-center, 7-month FU	Performance	Implant: I1 Sound processor: SP2	Subset of patient group 1	10	Completed
BC114	Prospective, single-center, 2-year FU	Performance	Implant: I1 Sound processor: Sentio 1 Mini	Subset of patient group 1	11	Completed primary endpoint analysis (1 month) 2y follow up ongoing
BC101	Prospective, multi-center 2-year FU	Safety & performance	Implant: Sentio Ti implant Sound processor: Sentio 1 Mini	Patient group 2		Completed primary endpoint analysis 2y follow up ongoing

C70	Virtual implantation of Sentio implant in CT scans	Investigate need for pre-operative planning	Implant: Sentio Ti implant Sound processor: NA	Patient group 3 (CT scans- no actual implantation performed)	197 CT scans (from 121 patients)	Completed

Table 5. Overview of human clinical investigations

Study BC101

A multicentre prospective study, including six clinics in three countries, using Sentio Ti implant and Sentio 1 Mini in the indicated population, has evaluated safety and performance three months after implantation. Fifty-one (51) adult patients (18 years or older) have been included in the study (Full Analysis Set (FAS)). The accumulated implant time for the 51 implanted patients is approximately 47 years and 29 and 16 subjects had performed 6-months and 12-months follow-up visits, respectively. A calibration error, resulting in less gain than intended being prescribed, impacts the 16 first included subjects (divided between two sites) and these are excluded from the per protocol analysis set used for conclusions on performance. The clinical investigation report shows that main hypotheses can be proven with both per protocol and full analysis sets and that performance and safety for the Sentio system are verified. The study continues to run with full cohort 24-months data expected in Q4 2025. The Sentio system compensates for hearing loss, i.e. improves the hearing for patients within the indicated use manifested by improved ability to hear sounds (reduced disability) and improved speech intelligibility. The normal hearing threshold for pure tones is 20 dB HL and normal speech level is around 65 dB SPL, thus the average aided threshold results, 26.3 dB HL (PPS) and 26.3 dB (FAS) show that patients can hear sounds at normal speech levels with the Sentio system. The average functional gain was 32.8 dB (PPS) and 29.3 dB (FAS); in line with what has been reported for similar devices. Speech recognition in quiet is significantly improved with the Sentio system compared to unaided for patients with conductive and mixed hearing losses as well as patients with single sided deafness. The speech intelligibility in quiet (at 65 dB SPL) across the intended population is 97.9% (PPS) and 97.6% (FAS). Subjective measures, in the form of standardized questionnaires, complement and support the objective data. The BC101 study used the Glasgow benefit inventory (GBI), a generic health-related quality of life questionnaire developed specifically for otorhinolaryngological interventions, where scores above 0 indicate improved quality of life. On average, the total GBI score across studies was 28.4 (PPS) and 29.2 (FAS). On an individual level 97.1% (PPS), and 96.1% (FAS), reported an improvement in quality of life using the Sentio system. No serious adverse device-related events or major complications were reported across the indicated population. The minor complications (such as dizziness/headache, numbness, swelling or erythema, pain at surgical site, and sound sensations) reported were transient and/or of mild intensity. The safety profile is in line with similar devices and the reported adverse events do not reflect any new type of risk than what has been previously identified. The study concludes that the primary end-points (improved hearing and improved speech recognition on the implanted ear) were statistically significant in favor of the Sentio when compared to reference values. No major complications were reported. Based on the number, severity, duration, and type of reported adverse event, the Sentio system is safe to use as intended. Safety and performance will be evaluated again, six months after implantation, and long-term safety and performance will be evaluated at 24-months follow-up. ClinicalTrials.gov Identifier: NCT05166265

BC101 sub study

To further evaluate the patient experience of undergoing an MRI with the Sentio Ti implant a clinical sub-study to the ongoing pivotal study of the Sentio system (ClinicalTrials.Gov NCT05628285) was conducted. Nine patients voluntarily participated in the study. After the scans (all patients underwent head MRI scans), both the patients and the clinicians completed a questionnaire about their experience. Occurrence of adverse events was followed for two weeks. The patients rated their experience of various aspects, such as pain and pressure, on a scale (Numeric Rating Scale, NRS) of 0-10. The MRI was completed successfully in all nine cases without any complications or adverse events. Patients generally had a positive experience with an average rating of 2. As expected, there was some mild pressure at the implant site (average score of 3) and a few patients experienced mild pain due to the pressure (average score of 1). It is concluded that the clinical data supports that patients with a Sentio Ti implant can safely undergo a 1.5T MRI as per the outlined conditions.

Additional clinical data

Study O1 (1y follow-up): This clinical study included treatment with the first design iteration of the implant (I1, in the study documentation denoted the BCI implant/BBC) and sound processor SP1. The study was a consecutive prospective multi-centre study with the purpose to demonstrate that the system (I1 and SP1) was safe and performing as expected. The study included 16 patients implanted between 11 November 2012 and 27 November 2016. Follow-up visits were conducted at 7-10 days, 4-6 weeks (sound processor fitting), and at 3, 6, and 12 months post-operatively. Main outcome measures were intraoperative and postoperative safety (complications and adverse events), as well as outcome measures related to the effectiveness of the device in terms of audiological performance. In summary it was concluded that the procedure for installing I1 is safe, and the transmission condition was stable over the follow-up time. Improvements were seen in hearing thresholds, speech reception thresholds, speech in noise recognition, and patient reported satisfaction when comparing the aided to the unaided condition. Similar or better hearing thresholds, speech reception thresholds, speech in noise recognition, and patient reported satisfaction are demonstrated compared to a conventional bone conduction device.

Study O1 (5y follow-up): In a continuation of the clinical study described above, a subset of the patients with the first design iteration of the implant (I1) continued to be followed up at three and five years after enrolment/implantation. The aim was to report on audiometric results and patient-reported outcome measures from quality-of-life. No serious adverse events or serious adverse device effects occurred during the follow-up time confirming long-term safety. By using the system, the patients got significantly improved sensitivity (measured by hearing thresholds and speech reception thresholds), speech in noise recognition and self-assessment (questionnaire) results than compared both to the unaided condition (primary effect hypothesis) and to a conventional bone conduction device (secondary effect hypothesis). It has been shown that the effectiveness of the device in terms of audiological performance is persistent over time (5 years), thus confirming long-term effectiveness.

Study C58: After 1 year a sub-set of the patients (ten subjects) enrolled in study O1 were upgraded with the SP2 sound processor. The study was a single-centre prospective case study with the primary objective to validate the performance of the SP2 in terms of improvement in aided thresholds compared to the unaided condition. Secondary objectives included speech intelligibility with the SP2 comparing unaided to aided thresholds and speech intelligibility with SP2 over time (7 months) and compared to SP1. In addition, the study evaluated adverse events, potential skin problems, processor retention force, as well as subjective benefit,

satisfaction, and usability. The results confirmed that SP2, together with the I1 implant, gave a significant functional gain benefit of 29.6 dB. In addition, SP2 gave benefit to the users in terms of improved speech intelligibility compared to unaided condition. The performance of SP2 was stable over time and similar to SP1. Very few skin reactions were reported, and retention and comfort were rated similar to the SP1. Few adverse events and no serious adverse events were reported in the study. No new safety risks were identified. ClinicalTrials.gov Identifier: NCT03374787

Study BC114: After closure of study C58, all patients from the study O1 cohort were upgraded to Sentio 1 Mini sound processor. Eleven subjects accepted to participate in the study and were upgraded with the Sentio 1 Mini. One subject was lost to follow-up. The study is a pre-market, prospective, single-centre, comparative study with within-subject control design. The primary objective was to assess the improvement of hearing with Sentio 1 Mini. Secondary objectives included patient reported outcomes and collection of adverse events throughout the study. The performance end-point for the primary objective was the difference between Sentio 1 Mini aided sound field thresholds and unaided sound field thresholds (functional gain) PTA4 (500, 1000, 2000, 4000Hz). Results showed a significant improvement in average functional gain of 32.5 dB (SD: 6.8). The difference between aided sound field thresholds and unaided sound field thresholds was shown to be significant for all measured frequencies. The effective gain showed an average effective gain of 11.9 dB PTA4 (SD: 7.7). The abbreviated Speech, Spatial and Qualities of hearing scale (SSQ12), was used to collect self-reported performance related to the subject's previous sound processor and at the 1-month follow up for the Sentio 1 Mini. There were no significant differences observed between the two devices at either the subgroup level (speech, spatial, quality) or in the overall total. A preference assessment showed that most subjects (7 out of 10) preferred the Sentio 1 Mini over their previous sound processor. Two subjects had no preference, and one had a slight preference for his/her previous sound processor. In conversation situations all subjects either preferred the Sentio 1 Mini or had no preference, while for sound quality and loudness aspects one to two subjects preferred the previous device. Up until the 1-month follow-up no adverse events or device deficiencies had occurred. ClinicalTrials.gov Identifier: NCT05628285

Study C70: The objective of the study was to increase the knowledge about bone thickness in the relevant area for implantation of the Sentio Ti implant in order to develop surgical strategy and pre-operative planning. The study was a retrospective and non-interventional study performed on CT scans, on file at the investigator, using the final design of the implant (Sentio Ti implant). In conclusion, in adults without known medical history that indicates anatomical malformations, the average minimum bone thickness in the combined recess and screw area was 5.55 ± 1.46 mm, with a 95% confidence interval of 5.30–5.80 mm, i.e., thicker than both the maximum transducer depth of 3 mm and the 2.7 mm bone engagement of the osseointegrating fixation screws.

Devices changes

Both design iterations of the implant (I1 and Sentio Ti implant) have the same mode of operations and main elements; a receiving inductive link, a holding magnet and a transducer. Except for the housing of the transducer the dimensions of the implant are similar. The implant is surgically placed under the skin and periosteum in the temporal bone area under general or local anesthesia. The transducer is placed in a recess and fixed to the bone; the lower profile of the Sentio Ti allows for a slightly shallower recess than the I1. The sound processor is held against the implant with a magnetic retention system. The different design iterations have slightly different size and weight. A tamper resistant battery door was introduced in the final

design (Sentio 1 Mini). The design iterations have different sound processing features and Sentio 1 Mini has Bluetooth functionality.

For efficacy, a comparison of maximum force output (MFO) can be used to verify that combinations of implants and sound processors give similar maximum force output (MFO). Based on the comparison of the Sentio system, it is concluded that the MFO differences between the different design iterations are not expected to be clinically significant. From an efficacy standpoint, similar performance will therefore be expected from the different design iterations, including the final design Sentio Ti implant and Sentio 1 Mini sound processor.

L. Conclusion

It is concluded that the Sentio Active Implantable Bone Conduction Hearing System is substantially equivalent to the predicate devices MED-EL Bonebridge system (DEN170009) and comparable to the reference device Oticon Medical Ponto 5 SuperPower (K213733). The minor technological differences between the Sentio system devices and their predicate devices raise no new issues of safety or effectiveness.