



# DECLARATION OF CONFORMITY

According to EU Regulation 2017/745

DoC-2021-04

## Declaration of Conformity

1. **Legal Manufacturer:** **Advanced Bionics, LLC**  
28515 Westinghouse Place  
Valencia, CA 91355  
USA
2. **Manufacturing Sites:** **Advanced Bionics, LLC**      **Advanced Bionics, LLC**  
12740 San Fernando Road.      28515 Westinghouse Place  
Sylmar, CA 91342      Valencia, CA 91355  
USA      USA
3. **Authorized Representative:** **Advanced Bionics GmbH**  
Feodor-Lynen-Strasse 35  
DE-30625 Hannover  
Germany
4. **Object of the Declaration:** **HiResolution™ Bionic Ear System**
5. **Single Registration Number (SRN):**
6. **Notified Body:** **TÜV SÜD Product Service GmbH**  
*Address:* Ridlerstrasse 65, 80339 München, Germany  
*ID Number:* NB 0123  
*Scope Expression:* MDA 0101  
*Conformity Assessment Route:* Annex IX of the Regulation (EU) 2017/745
7. **The legal manufacturer maintains a Quality System in compliance with the EN ISO 13485:**  
  
*Certificate QMS:*      Q5 077725 0004 Rev. 00      *Valid Until:* 2022-04-24
8. **The legal manufacturer declares under their sole responsibility that the object of the declaration is in conformity with the Medical Device Regulation (EU) 2017/745 and certified according to its Annex IX for the Complete Quality Assurance System.**  
  
*Certificate EU Quality Management System*      G12 077725 0021 Rev.01      *Valid Until:* 2026-01-27  
*Certificate DE, Annex IX*      listed below
9. **Medical device risk class:** **Class III Annex IX of the Regulation (EU) 2017/745**
10. **Valid from:** **2021-04-20**





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## 11. Products covered by this Declaration of Conformity

EC DE Certificate: G70 077725 0022 Rev. 00

Valid Until: 2026-04-14

Product Scope: Cochlear Implants

| Model No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Model Name                                  | Basic UDI-DI       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------|
| CI-1600-04                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | HiRes™ Ultra CI HiFocus™ MS Electrode       | 08400944CI160004PV |
| <b>INTENDED PURPOSE</b><br>The HiRes™ Ultra CI HiFocus™ MS Electrode cochlear implant is an auditory active implantable device in the HiResolution™ Bionic Ear System. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The HiRes™ Ultra CI HiFocus™ MS Electrode cochlear implant receives power and sound data over an inductively coupled link from the external sound processor system and converts the sound data into electrical stimulation which is delivered to the auditory nerve via the pre-curved electrode array to enable hearing.                                                                                                                                                                                     |                                             |                    |
| CI-1600-05                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | HiRes™ Ultra CI HiFocus™ SlimJ Electrode    | 08400944CI160005PX |
| <b>INTENDED PURPOSE</b><br>The HiRes™ Ultra CI HiFocus™ SlimJ Electrode cochlear implant is an auditory active implantable device in the HiResolution™ Bionic Ear System. The HiResolution™ Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The HiRes™ Ultra CI HiFocus™ SlimJ Electrode cochlear implant receives power and sound data over an inductively coupled link from the external sound processor system and converts the sound data into electrical stimulation which is delivered to the auditory nerve via the lateral wall electrode array to enable hearing.                                                                                                                                                                            |                                             |                    |
| CI-1601-04                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | HiRes™ Ultra 3D CI HiFocus™ MS Electrode    | 08400944CI160104Q2 |
| <b>INTENDED PURPOSE</b><br>The HiRes™ Ultra 3D HiFocus™ MS Electrode cochlear implant is an auditory active implantable device in the HiResolution™ Bionic Ear System. The HiResolution™ Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The HiRes™ Ultra CI HiFocus™ MS Electrode cochlear implant receives power and sound data over an inductively coupled link from the external sound processor system and converts the sound data into electrical stimulation which is delivered to the auditory nerve via the pre-curved electrode array to enable hearing. A self-aligning internal magnet allows the cochlear implant to be scanned at 1.5T and 3.0T at any orientation within the MRI scanner without bandaging and without magnet removal. |                                             |                    |
| CI-1601-05                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | HiRes™ Ultra 3D CI HiFocus™ SlimJ Electrode | 08400944CI160105Q4 |
| <b>INTENDED PURPOSE</b><br>The HiRes™ Ultra 3D HiFocus™ SlimJ Electrode cochlear implant is an auditory active implantable device in the HiResolution™ Bionic Ear System. The HiResolution™ Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                             |                    |





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profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The HiRes™ Ultra CI HiFocus™ SlimJ Electrode cochlear implant receives power and sound data over an inductively coupled link from the external sound processor system and converts the sound data into electrical stimulation which is delivered to the auditory nerve via the lateral wall electrode array to enable hearing. A self-aligning internal magnet allows the cochlear implant to be scanned at 1.5T and 3.0T at any orientation within the MRI scanner without bandaging and without magnet removal.

EC DE Certificate:

G70 077725 0019 Rev. 00

Valid Until:2026-01-25

Product Scope:

External Components for Cochlear Implant Systems

| Model No.   | Model Name                                 | Basic UDI-DI     |
|-------------|--------------------------------------------|------------------|
| CI-5293-110 | Naída™ CI M90 Sound Processor alpine white | 08400944CI5293YE |
| CI-5293-120 | Naída™ CI M90 Sound Processor sand beige   | 08400944CI5293YE |
| CI-5293-130 | Naída™ CI M90 Sound Processor chestnut     | 08400944CI5293YE |
| CI-5293-140 | Naída™ CI M90 Sound Processor silver gray  | 08400944CI5293YE |
| CI-5293-150 | Naída™ CI M90 Sound Processor velvet black | 08400944CI5293YE |
| CI-5293-240 | Naída™ CI M90 Sound Processor resin beige  | 08400944CI5293YE |

## INTENDED PURPOSE

The Naída™ CI M90 sound processor is an accessory of an auditory active implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The Naída™ CI M90 sound processor is a behind the ear (BTE) sound processor which works together with the implant to bypass the damaged part of the inner ear and converts sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.

The Naída™ CI M90 is the premium version with full access to multiple automatic programs and features including bimodal and bilateral and supports compatibility with acoustic amplification.

|             |                                            |                  |
|-------------|--------------------------------------------|------------------|
| CI-5294-120 | Naída™ CI M30 Sound Processor sand beige   | 08400944CI5294YG |
| CI-5294-130 | Naída™ CI M30 Sound Processor chestnut     | 08400944CI5294YG |
| CI-5294-140 | Naída™ CI M30 Sound Processor silver gray  | 08400944CI5294YG |
| CI-5294-150 | Naída™ CI M30 Sound Processor velvet black | 08400944CI5294YG |
| CI-5294-240 | Naída™ CI M30 Sound Processor resin beige  | 08400944CI5294YG |

## INTENDED PURPOSE

The Naída™ CI M30 sound processor is an accessory of an auditory active implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory





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sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The Naída™ CI M30 sound processor is a behind-the-ear (BTE) sound processor which works together with the implant to bypass the damaged part of the inner ear and converts sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.

The Naída™ CI M30 is the essential version with basic automatic programs and features.

|             |                                              |                  |
|-------------|----------------------------------------------|------------------|
| CI-5295-110 | Sky CI™ M90 Sound Processor alpine white     | 08400944CI5295YJ |
| CI-5295-120 | Sky CI™ M90 Sound Processor sand beige       | 08400944CI5295YJ |
| CI-5295-130 | Sky CI™ M90 Sound Processor chestnut         | 08400944CI5295YJ |
| CI-5295-140 | Sky CI™ M90 Sound Processor silver gray      | 08400944CI5295YJ |
| CI-5295-150 | Sky CI™ M90 Sound Processor velvet black     | 08400944CI5295YJ |
| CI-5295-190 | Sky CI™ M90 Sound Processor caribbean pirate | 08400944CI5295YJ |
| CI-5295-240 | Sky CI™ M90 Sound processor resin beige      | 08400944CI5295YJ |
| CI-5295-250 | Sky CI™ M90 Sound Processor precious pink    | 08400944CI5295YJ |
| CI-5295-260 | Sky CI™ M90 Sound processor blue ocean       | 08400944CI5295YJ |
| CI-5295-270 | Sky CI™ M90 Sound processor majesty purple   | 08400944CI5295YJ |
| CI-5295-280 | Sky CI™ M90 Sound processor lava red         | 08400944CI5295YJ |

### INTENDED PURPOSE

The Sky CI™ M90 sound processor is an accessory of an auditory active implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The Sky CI™ M90 sound processor is a behind-the-ear (BTE) sound processor which works together with the implant to bypass the damaged part of the inner ear and converts sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.

The Sky CI™ M90 sound processor can be used by both adults and children, and provides dedicated pediatric hearing solution (multiple color options, and adjustable program for individual pediatric users). The Sky CI™ M90 provides full access to multiple automatic programs and features including bimodal and bilateral and supports compatibility with acoustic amplification.





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**EC DE Certificate:**  
**Product Scope:**

**G70 077725 0020 Rev.00**  
**Application Software for Cochlear Implant Systems**

*Valid Until:2026-01-26*

| Model No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Model Name | Basic UDI-DI     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------------|
| CI-6057-001                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Target CI  | 08400944CI6057Y7 |
| <b>INTENDED PURPOSE</b><br>The Target CI fitting software is an accessory of an auditory active implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear System is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant of the HiResolution Bionic Ear System to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.<br>The Target CI fitting software from Advanced Bionics is intended to be used by qualified hearing care professionals to configure, program, and fit compatible sound processors to patient-specific requirements. It is not worn by the recipient and there is no minimum or maximum limit on the time that the software can be used. |            |                  |
| CI-6058-001                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | AB Remote  | 08400944CI6058Y9 |
| <b>INTENDED PURPOSE:</b><br>The AB Remote app is an accessory of an auditory active implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant of the HiResolution Bionic Ear system to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing<br>The AB Remote app is designed to be used with Advanced Bionics' Naída CI M and Sky CI M sound processors to allow the user to control volume related and program settings, as well as accessing additional helpful information.                                                                                                                   |            |                  |





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EC DE Certificate:

G70 077725 0018 Rev.00

Valid Until:2026-01-26

Product Scope:

External Components for Cochlear Implant Systems

| Model No.   | Model Name          | Basic UDI-DI     |
|-------------|---------------------|------------------|
| CI-5320-001 | Slim HP 3.5" beige  | 08400944CI5320XQ |
| CI-5320-002 | Slim HP 3.5" black  | 08400944CI5320XQ |
| CI-5320-003 | Slim HP 3.5" brown  | 08400944CI5320XQ |
| CI-5320-004 | Slim HP 3.5" gray   | 08400944CI5320XQ |
| CI-5320-005 | Slim HP 3.5" white  | 08400944CI5320XQ |
| CI-5320-006 | Slim HP 4.25" beige | 08400944CI5320XQ |
| CI-5320-007 | Slim HP 4.25" black | 08400944CI5320XQ |
| CI-5320-008 | Slim HP 4.25" brown | 08400944CI5320XQ |
| CI-5320-009 | Slim HP 4.25" gray  | 08400944CI5320XQ |
| CI-5320-010 | Slim HP 4.25" white | 08400944CI5320XQ |
| CI-5320-011 | Slim HP 5.5" beige  | 08400944CI5320XQ |
| CI-5320-012 | Slim HP 5.5" black  | 08400944CI5320XQ |

## INTENDED PURPOSE

The Slim HP headpieces are part of the external components of an auditory active-implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.

The Slim HP is a headpiece with an integrated cable designed for use with a sound processor on the ear and is intended to transfer sound signals and power between Advanced Bionics' cochlear implant and sound processor.

|             |                           |                  |
|-------------|---------------------------|------------------|
| CI-5321-001 | Slim HP AquaMic 12" beige | 08400944CI5321XS |
| CI-5321-002 | Slim HP AquaMic 12" black | 08400944CI5321XS |
| CI-5321-003 | Slim HP AquaMic 12" brown | 08400944CI5321XS |
| CI-5321-004 | Slim HP AquaMic 12" gray  | 08400944CI5321XS |
| CI-5321-005 | Slim HP AquaMic 18" beige | 08400944CI5321XS |
| CI-5321-006 | Slim HP AquaMic 18" black | 08400944CI5321XS |
| CI-5321-007 | Slim HP AquaMic 18" brown | 08400944CI5321XS |





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|             |                           |                  |
|-------------|---------------------------|------------------|
| CI-5321-008 | Slim HP AquaMic 18" gray  | 08400944CI5321XS |
| CI-5321-009 | Slim HP AquaMic 24" beige | 08400944CI5321XS |
| CI-5321-010 | Slim HP AquaMic 24" black | 08400944CI5321XS |
| CI-5321-011 | Slim HP AquaMic 24" brown | 08400944CI5321XS |
| CI-5321-012 | Slim HP AquaMic 24" gray  | 08400944CI5321XS |
| CI-5321-013 | Slim HP AquaMic 42" beige | 08400944CI5321XS |
| CI-5321-014 | Slim HP AquaMic 42" black | 08400944CI5321XS |
| CI-5321-015 | Slim HP AquaMic 42" brown | 08400944CI5321XS |
| CI-5321-016 | Slim HP AquaMic 42" gray  | 08400944CI5321XS |

### INTENDED PURPOSE

The Slim HP AquaMic™ headpieces are part of the external components of an auditory active-implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing. The Slim HP AquaMic™ is a headpiece with an integrated cable and a microphone designed for use in water environments. It is intended to transfer sound signals and power between Advanced Bionics' cochlear implant and sound processor. The embedded microphone, if enabled, allows the headpiece to also function as a sound input source.

|             |                       |                  |
|-------------|-----------------------|------------------|
| CI-5322-001 | Slim HP Mic 12" black | 08400944CI5322XU |
|-------------|-----------------------|------------------|

### INTENDED PURPOSE

The Slim HP Mic headpieces are part of the external components of an auditory active-implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing. The Slim HP Mic is a headpiece with an integrated cable and a microphone designed for use with a sound processor worn off the ear. It is intended to transfer sound signals and power between Advanced Bionics' cochlear implant and sound processor. The embedded microphone, if enabled, allows the headpiece to also function as a sound input source.

|         |                  |                  |
|---------|------------------|------------------|
| CI-5323 | Slim HP Standard | 08400944CI5323XW |
|---------|------------------|------------------|

**INTENDED PURPOSE:** The Slim HP Standard is an external component of an auditory active implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals





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with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.

The Slim HP Standard is a headpiece that uses separate cables and is designed to be worn on the ear. It is intended to transfer sound signals and power between your Advanced Bionics' cochlear implant and sound processor.

|             |                             |                  |
|-------------|-----------------------------|------------------|
| CI-5851-001 | M Acoustic Earhook Right 00 | 08400944CI5851YU |
| CI-5851-002 | M Acoustic Earhook Right 0  | 08400944CI5851YU |
| CI-5851-003 | M Acoustic Earhook Right 1  | 08400944CI5851YU |
| CI-5851-004 | M Acoustic Earhook Right 2  | 08400944CI5851YU |
| CI-5851-005 | M Acoustic Earhook Right 3  | 08400944CI5851YU |
| CI-5851-006 | M Acoustic Earhook Left 00  | 08400944CI5851YU |
| CI-5851-007 | M Acoustic Earhook Left 0   | 08400944CI5851YU |
| CI-5851-008 | M Acoustic Earhook Left 1   | 08400944CI5851YU |
| CI-5851-009 | M Acoustic Earhook Left 2   | 08400944CI5851YU |
| CI-5851-010 | M Acoustic Earhook Left 3   | 08400944CI5851YU |

### INTENDED PURPOSE:

The M Acoustic Earhook is an external component of an auditory active implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing. The M Acoustic Earhook provides acoustic amplification for patients with aid able low frequency hearing.

The M Acoustic Earhook coupled with the Naída CI M90 or Sky CI M90 sound processor is intended to provide acoustic amplification and electrical stimulation to Advance Bionics cochlear implant recipients.





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**12. Signed for and on behalf of: Advanced Bionics**

*Date of issue:* 2021-04-20  
*Place of issue:* Hannover, Germany

Author

2021-04-20

Aniko Bardi  
Senior Regulatory Affairs Specialist  
Advanced Bionics

Date

Reviewer

Kemine Hale  
Senior Manager Regulatory &  
Clinical Affairs, PRRC-AR  
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2021-04-20

Date