



EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 077725 0018 Rev. 00

Manufacturer:

Advanced Bionics, LLC

28515 Westinghouse Place
Valencia CA 91355
USA

**Authorized
Representative:**

Advanced Bionics GmbH
Feodor-Lynen-Str. 35, 30625 Hannover, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 077725 0018 Rev. 00

Report No.:

713187189

Valid from:

2021-01-27

Valid until:

2026-01-26

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2021-01-27



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Classification:	III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	08400944CI5851YU
Intended Purpose:	<p>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 aidable 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.</p>
Device(s):	<p>M Acoustic Earhook Right 00, CI-5851-001; M Acoustic Earhook Right 0, CI-5851-002; M Acoustic Earhook Right 1, CI-5851-003; M Acoustic Earhook Right 2, CI-5851-004; M Acoustic Earhook Right 3, CI-5851-005; M Acoustic Earhook Left 00, CI-5851-006; M Acoustic Earhook Left 0, CI-5851-007; M Acoustic Earhook Left 1, CI-5851-008; M Acoustic Earhook Left 2, CI-5851-009; M Acoustic Earhook Left 3, CI-5851-010;</p>
Classification:	III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	08400944CI5323XW
Intended Purpose:	<p>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 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</p>



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	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.
Device(s):	Slim HP Standard; CI-5323
Classification:	III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	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.
Device(s):	Slim HP Mic; CI-5322-001
Classification:	III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	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



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Device(s):

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.

Slim HP AquaMic™
AquaMic 12"
beige, CI-5321-001;
black, CI-5321-002;
brown, CI-5321-003;
gray, CI-5321-004;
AquaMic 18"
beige, CI-5321-005;
black, CI-5321-006;
brown, CI-5321-007;
gray, CI-5321-008;
AquaMic 24"
beige, CI-5321-009;
black, CI-5321-010;
brown, CI-5321-011;
gray, CI-5321-012
AquaMic 42"
beige, CI-5321-013;
black, CI-5321-014;
brown, CI-5321-015;
gray, CI-5321-016;

Classification:

III

Device Group:

J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES -
ACCESSORIES

Basic UDI-DI:

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.



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Device(s):

Slim HP
3.5" beige, CI-5320-001;
3.5" black, CI-5320-002;
3.5" brown, CI-5320-003;
3.5" gray, CI-5320-004;
3.5" white, CI-5320-005;
4.25" beige, CI-5320-006;
4.25" black, CI-5320-007;
4.25" brown, CI-5320-008;
4.25" gray, CI-5320-009;
4.25" white, CI-5320-010;
5.5" beige, CI-5320-011;
5.5" black, CI-5320-012;

**The validity of this certificate
depends on conditions and/or
is limited to the following:** -None-