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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Hanna Kozakiewicz

Dokument podpisany przez Hanna Kozakiewicz
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TÜV SÜD Product Service

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 0020 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 0020 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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No. G70 077725 0020 Rev. 00

Classification:	III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	08400944CI6057Y7
Intended Purpose:	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 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. 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.
Device(s):	Target CI, CI-6057-001

Classification:	III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	08400944CI6058Y9
Intended Purpose:	The AB Remote app is an accessory of an auditory active implantable system, the HiResolution Bionics 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 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 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.
Device(s):	AB Remote, CI-6058-001

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

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