K121793

1. 510(k) Summary

NOV 1 2012

In accordance with 21 CFR 807.92

Applicant's Name and Address:	audifon USA, Inc 403 Chairman Court, Suite 1 Debary, FL 32713 U.S.A.
Establishment Registration Number	3005384855
Contact Person:	Jane Perrone Phone 1 800 776 0222 Fax 1 386 753 9564 E-mail: jane.perrone@audifon-usa.com
Date of submission:	06/13/2012
Proprietary Name:	An Evo1.....(bone conduction hearing aid) contact star evo1.....(bone conduction hearing aid) contact mini.....(bone conduction hearing aid) apollon.....(bone conduction hearing aid)
Device Common Name	Hearing Aid, Bone Conduction
Product Code	LXB
Classification of Device	Class: II Panel: Ear, Nose and Throat Regulation Number: 874.3300
Address of Manufacturing Site	BHM-Tech Produktionsgesellschaft mbH Grafenschachen 242 A-7423 Grafenschachen Austria
Predicate Device	K935701 Starkey Laboratories Inc. VIENNATONE AN, VIENNATONE AS FIDELITY F228, FIDELITY F229

Indications for use: Bone conduction hearing aids by BHM-Tech are wearable sound-amplifying devices intended to compensate impairments in personal hearing. The fundamental operating principle is to receive, amplify, and transfer sound via the skin and the bone of the skull to the inner ear of a hearing impaired person. The amplification suits the needs of a mild to a moderate hearing loss. They require individual fitting in performance executed by a hearing aid professional.

The target populations for the devices are as follows:

AN-Evo1	adults and children (≥ 12 years)
contact star evo1	adults and children (≥ 12 years)
contact mini	adults and children (≥ 8 months)
apollon	adults and children (≥ 12 years)

The apollon is a device where it is capable of utilizing either air or bone conduction.

Description of Devices

AN-Evo1

Different to the more common air conduction hearing devices, with digital bone conducted hearing aids AN-Evo1 the sound is produced in a small vibrator and transmitted by direct contact to the mastoid. From here the sound is transmitted via the skull to the inner ear and transformed directly into nerve impulses.

The AN-Evo1 is a hearing aid battery powered, programmable, digital, bone conduction hearing aid which can be mounted onto different aid front-models. For mounting, extension tips and aid-fronts with different mechanical dimensions (lengths of extension tips, size of aid-fronts) are available. The AN-Evo1 is also available in different colors (black, brown and anthracite).
It can be used monaural or binaural. For monaural, the hearing aid has one active temple and one none-active temple (dummy-temple). For binaural, the hearing aid has two active temples.

The AN-Evo1 includes a digital programmable amplifier and a bone vibrator unit, which are connected directly in one housing. The bone vibrator of the device is held against the head and is driven electrically by the amplifier to transmit the amplified sound as vibrations to the underneath bones of the skull. It also has a built in microphone for picking up sound and a built in induction coil for picking up magnetic fields from induction loop systems. For selecting the operating mode, a three position mode switch is used. The positions are O, OFF, T. Telecoil (induction coil) and M. Microphone. A Volume Control wheel is used to adjust the output power of the device.

The AN-Evo1 is programmable via the HIPRO-Programming Box and BHMFit2 Fittingsoftware. The fitting will only be conducted by an audiologist, a hearing aid specialist or ENT.

contact star evo1

Different to traditional air conduction hearing devices, by using bone conduction hearing aids contact star-evo1 the sound is produced in a broadband miniature vibration receiver and transmitted by direct skin contact to the mastoid, the area of the temple bone behind the ear. From here it is transmitted through the skull to the inner ear, where it is transformed into nerve impulses.

The contact star evo1 is a hearing aid battery powered, programmable, digital, bone conduction hearing aid which can be mounted onto different aid front-models. For mounting, extension tips

and aid-fronts with different mechanical dimensions (lengths of extension tips, size of aid-fronts) are available. The contact star evo1 is also available in different colors (black, brown and anthracite).

It can be used monaural or binaural. For monaural, the hearing aid has one active temple and one none-active temple (dummy-temple). For binaural, the hearing aid has two active temples.

The contact star evo1 includes a high performance digital programmable amplifier and a bone vibrator unit, which are connected directly in one housing. The bone vibrator of the device is held against the head and is driven electrically by the amplifier to transmit the amplified sound as vibrations to the underneath bones of the skull. It also has a built in microphone for picking up sound and a built in induction coil for picking up magnetic fields from induction loop systems. For selecting the operating mode, a three position mode switch is used. The positions are O..OFF, T..Telecoil (induction coil) and M..Microphone. A Volume Control wheel is used to adjust the output power of the device.

The contact star evo1 is programmable via the HIPRO-Programming Box and BHMFit2 programming software. The fitting will only be conducted by an audiologist, a hearing aid specialist or ENT.

contact mini

The contact mini is a digital bone conduction hearing aid. Sound is transmitted directly through the bones of the skull to the cochlea, bypassing the outer and middle ear.

Contact mini consists of two interconnected units. An amplifier module and an bone vibrator. The amplifier module and the bone vibrator are connected through a wire cable. The amplifier module amplifies the sound and the bone vibrator converts them into vibrations. The bone vibrator has direct contact with the skin. The amplified sound moves through the bones of the skull to the inner ear, where it is directly converted into a neural stimulus.

The contact mini is a hearing aid battery powered, programmable, digital, bone conduction hearing aid which can be mounted onto different wearing such as headband, circlets and baseball caps. The contact mini is also available in different colors (black, blue and red).

It can be used monaural or binaural. For monaural, the hearing aid use one active device and one bone vibrator. For binaural, the hearing aid uses two active devices and two bone vibrators.

The contact mini includes a high performance digital programmable amplifier. The amplifier module is completely self-contained and has also a built in microphone for picking up sound. A Volume Control trimmer is used to adjust the output power of the device.

The contact mini is programmable via the HIPRO-Programming Box and BHMFit2 programming software. The fitting will only be conducted by an audiologist, a hearing aid specialist or ENT.

apollon

The apollon is also a bone conduction hearing aid. Unlike conventional hearing aids which depend upon acoustic coupling through air, the apollon is based on bone conduction technology. Sound is transmitted directly through the bones of the skull to the cochlea, bypassing the outer and middle ear.

The apollon consists of a bone vibrator unit, a shirt pocket sized amplifier module and a wire cable for connecting the bone vibrator with the amplifier module. The bone vibrator is a

convenient sized unit that is held against the head and is driven electrically to transmit the amplified sound as vibrations to the underneath bones of the skull.

The amplifier module connects the bone vibrator through the wire cable and usually would be carried in the users pocket. The amplifier module is completely self-contained and is battery powered. It also has a built in microphone for picking up sound and a built in induction coil for picking up magnetic fields from induction loop systems. As an added feature an auxiliary 3,5mm input jack allows the user to connect the apollon directly to TV, MP3 players, portable radios or even telephones without any additional adaptors. For selecting the operating mode, a four position mode switch is used. The positions are O..OFF, T..telecoil (induction coil), MT..microphone & telecoil (induction coil) and M..microphone. A Volume Control is used to adjust the output power of the device.
Also, the possibility of a connection between via the DAI (Direct Audio Input) is available. A red LED (Light Emitting Diode) is used for optical low battery warning.

The apollon is equipped with an high performance digital programmable amplifier system which can be adjusted via the BHMFit2 Programming software. The fitting will only be conducted by an audiologist, an hearing aid specialist or ENT.

Comparison Tables

	AN-Evo1	Viennatone AN - Fidelity F228
Intended Use	Hearing Aid, Bone Conduction	Hearing Aid, Bone Conduction
Indications For Use	For mild to moderate hearing losses	For most severe hearing loss
Target Population	adults and children (>= 12 years)	adults and children
Materials	Medical Grade plastics	Medical Grade plastics
Operation / Mechanism	Circuit type: Digital Programmable: Yes Channels: Two Volume control: Yes Mode switch: Yes Direct Audio Input: No Induction Coil: Yes Low Battery Indication: Yes Trimmer: Yes Program Switch Tones: Yes Output-Limitation: Yes,MPO Different Colors: Yes	Circuit type: Analog Programmable: No Channels: One Volume control: Yes Mode switch: Yes Direct Audio Input: No Induction Coil: Yes Low Battery Indication: No Trimmer: Yes Program Switch Tones: No Output-Limitation: Yes, Peak Clipping Different Colors: No
Technical Data Measured according DIN IEC 118-9; 1987	Maximum Output: 117 dBOFL Maximum Gain: 48 dB HFA-OSPL90: 113 dBOFL Telephone coil sensitivity: 94dB Equivalent input noise: 26 dB Battery current 1,2 mA Battery life time ~475 hours	Maximum Output 114 dBOFL Maximum Gain 46 dB HFA-OSPL90: 109 dBOFL Telephone coil sensitivity: 90dB Equivalent input noise: 30 dB Battery current 2,2 mA Battery life time ~260 hours
Where Used	May be used anywhere	May be used anywhere
Physical Description	Bone Conduction Aid which can be mounted with special Extension tips on different Eyeglasses.	Bone Conduction Aid which can be mounted with special Extension tips on different Eyeglasses.
Power Source	Battery type 675	Battery type 675

Abbreviations:

MPO	Maximum Peak Output
dBOFL	deci Bel Output Force Level

The AN-Evo1 is substantially equivalent to the Viennatone AN – Fidelity F228 (K935701). The AN-Evo1 differs from the Viennatone AN – Fidelity F228, in that the AN-Evo1 is a digital product with programmable characteristics, which increases the flexibility of fitting the device (Two

programmable channels are available, Low battery indication, Program switch tones). The AN-Evo1 is also available in different colors.
These differences are in the region of the production tolerances and do not affect the safety and effectiveness of the device when used as labeled.

	contact star evo1		Viennatone AS – Fidelity F229	
Intended Use	Hearing Aid, Bone Conduction		Hearing Aid, Bone Conduction	
Indications For Use	For mild to moderate hearing losses		For moderate to severe hearing losses	
Target Population	adults and children (>= 12 years)		adults and children	
Materials	Medical Grade plastics		Medical Grade plastics	
Operation / Mechanism	Circuit type: Programmable: Channels: Volume control: Mode switch: Direct Audio Input: Induction Coil: Low Battery Indication: Trimmer: Program Switch Tones: Output-Limitation: Different Colors:	Digital Yes Two Yes Yes No Yes Yes No Yes Yes, MPO Yes	Circuit type: Programmable: Channels: Volume control: Mode switch: Direct Audio Input: Induction Coil: Low Battery Indication: Trimmer: Program Switch Tones: Output-Limitation: Different Colors:	Analog No One Yes Yes No Yes No No No No Yes
Technical Data Measured according DIN IEC 118-9; 1987	Maximum Output: Maximum Gain: HFA-OSPL90: Telephone coil sensitivity: Equivalent input noise: Battery current Battery life time	110 dBOFL 50 dB 108 dBOFL 95dB 24 dB 1,2 mA ~500 hours	Maximum Output Maximum Gain HFA-OSPL90: Telephone coil sensitivity: Equivalent input noise: Battery current Battery life time	109 dBOFL 42 dB 105 dBOFL 88dB 28 dB 2,15 mA ~280 hours
Where Used	May be used anywhere		May be used anywhere	
Physical Description	Bone Conduction Aid which can be mounted with special Extension tips on different Eyeglasses.		Bone Conduction Aid which can be mounted with special Extension tips on different Eyeglasses.	
Power Source	Battery type 675		Battery type 675	

Abbreviations:
MPO Maximum Peak Output
dBOFL deci Bel Output Force Level

The contact star evo1 is substantially equivalent to the Viennatone AS – Fidelity F229 (K935701). The contact star evo1 differs from the Viennatone AS – Fidelity F229, in that the contact star evo1 is a digital product with programmable characteristics, which increases the flexibility of fitting the device (Two programmable channels are available, Low battery indication, Program switch tones, Output-Limitation).

These differences are in the region of the production tolerances and do not affect the safety and effectiveness of the device when used as labeled.

	contact mini		Viennatone AS – Fidelity F229	
Intended Use	Hearing Aid, Bone Conduction		Hearing Aid, Bone Conduction	
Indications For Use	For mild to moderate hearing losses		For moderate to severe hearing losses	
Target Population	adults and children (>= 8 months)		adults and children	
Materials	Medical Grade plastics		Medical Grade plastics	
Operation / Mechanism	Circuit type: Programmable: Channels: Volume control: Mode switch: Direct Audio Input: Induction Coil: Low Battery Indication: Trimmer: Program Switch Tones: Output-Limitation: Different Colors: Battery Compartment lock	Digital Yes Two Yes No No No Yes No Yes Yes, MPO Yes Yes	Circuit type: Programmable: Channels: Volume control: Mode switch: Direct Audio Input: Induction Coil: Low Battery Indication: Trimmer: Program Switch Tones: Output-Limitation: Different Colors: Battery Compartment lock	Analog No One Yes Yes No Yes No No No No Yes No
Technical Data Measured according DIN IEC 118-9; 1987	Maximum Output: Maximum Gain: HFA-OSPL90: Equivalent input noise: Battery current Battery life time	112 dBOFL 49 dB 107 dBOFL 22 dB 1,25 mA ~230 hours	Maximum Output Maximum Gain HFA-OSPL90: Equivalent input noise: Battery current Battery life time	109 dBOFL 42 dB 105 dBOFL 28 dB 2,15 mA ~280 hours
Where Used	May be used anywhere		May be used anywhere	
Physical Description	Bone Conduction Hearing aid which can be mounted on different wearing systems (Headbands, Circlets)		Bone Conduction Aid which can be mounted with special Extension tips on different Eyeglasses.	
Power Source	Battery type 13		Battery type 675	

Abbreviations:

MPO	Maximum Peak Output
dBOFL	deci Bel Output Force Level

The contact mini is substantially equivalent to the Viennatone AS – Fidelity F229 (K935701). The contact mini differs from the Viennatone AS – Fidelity F229, in that the contact mini is a digital product with programmable characteristics, which increases the flexibility of fitting the device (Two programmable channels are available, Low battery indication, Program switch tones, Output-Limitation, Battery Compartment lock). These differences are in the region of the

production tolerances and do not affect the safety and effectiveness of the device when used as labeled.

	apollon		Viennatone AN - Fidelity F228	
Intended Use	Hearing Aid, Bone Conduction		Hearing Aid, Bone Conduction	
Indications For Use	For mild to moderate hearing losses		For most severe hearing loss	
Target Population	adults and children (>= 12 years)		adults and children	
Materials	Medical Grade plastics		Medical Grade plastics	
Operation / Mechanism	Circuit type: Programmable: Channels: Volume control: Mode switch: Direct Audio Input: Induction Coil: Low Battery Indication: Trimmer: Program Switch Tones: Output-Limitation: Different Colors:	Digital Yes Four Yes Yes Yes Yes Yes No Yes Yes, MPO No	Circuit type: Programmable: Channels: Volume control: Mode switch: Direct Audio Input: Induction Coil: Low Battery Indication: Trimmer: Program Switch Tones: Output-Limitation: Different Colors:	Analog No One Yes Yes No Yes No Yes No Yes, Peak Clipping No
Technical Data Measured according DIN IEC 118-9; 1987	Maximum Output: Maximum Gain: HFA-OSPL90: Telephone coil sensitivity: Equivalent input noise: Battery current Battery life time	125 dBOFL 64 dB 115 dBOFL 94dB 26 dB 15,6 mA ~160 hours	Maximum Output Maximum Gain HFA-OSPL90: Telephone coil sensitivity: Equivalent input noise: Battery current Battery life time	114 dBOFL 46 dB 109 dBOFL 90dB 30 dB 2,2 mA ~260 hours
Where Used	May be used anywhere		May be used anywhere	
Physical Description	Bone Conduction Hearing aid which can be used in combination with an External Bone conductors (mounted on a Circlet)		Bone Conduction Aid which can be mounted with special Extension tips on different Eyeglasses.	
Power Source	2 AA Batteries		Battery type 675	

Abbreviations:

MPO	Maximum Peak Output
dBOFL	deci Bel Output Force Level

The apollon is substantially equivalent to the Viennatone AN – Fidelity F228 (K935701). The apollon differs in that it is a device where it is capable of utilizing either air or bone conduction. It is also a digital device which is programmable to the consumers needs by a hearing professional adding to its flexibility in fitting (Four programmable channels are available, Direct Audio Input, Low battery indication, Program switch tones, Output-Limitation). The apollon also uses a

different power source. These differences do not affect the safety and effectiveness of the device when used as labeled.

Risks to health

The AN-Evo1, contact star evo1, contact mini and apollon has the SAME intended use and does not raise different questions regarding safety and effectiveness. All patient skin contacting materials are manufactured from biocompatible materials that have been used in other medical devices. A User´s Instruction Guide is supplied with each hearing aid.

Hearing Healthcare Professional Diagnosis

The sale and fitting of the aids will only be conducted through a Hearing Healthcare Professional, such as an audiologist, hearing aid specialist or ENT.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 1 2012

Audifon-USA, Inc.
c/o Ms. Jane E. Perrone
VP of U.S. Operations
403 Chairman Ct., Suite 1
DeBary, FL 32713

Re: K121793
Trade/Device Name: An Evo 1, CS Evo 1, Contact Mini, Apollon
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: September 18, 2012
Received: September 25, 2012

Dear Ms. Perrone:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121793

5. Indications for Use Statement

510(k) Number (if known): K121793

Device Name:
AN-Evo1.....(bone conduction hearing aid)
contact star evo1.....(bone conduction hearing aid)
contact mini.....(bone conduction hearing aid)
apollon.....(bone conduction hearing aid)

Indications for use:
Bone conduction hearing aids by BHM-Tech are wearable sound-amplifying devices intended to compensate impairments in personal hearing.
The fundamental operating principle is to receive, amplify, and transfer sound via the skin and the bone of the skull to the inner ear of a hearing impaired person.
The amplification suits the needs of a mild to a moderate hearing loss.
They require individual fitting in performance executed by a hearing aid professional.

The target populations for the devices are as follows:

AN-Evo1	adults and children (≥ 12 years)
contact star evo1	adults and children (≥ 12 years)
contact mini	adults and children (≥ 8 months)
apollon	adults and children (≥ 12 years)

The apollon is a device where it is capable of utilizing either air or bone conduction.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K121793