DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 1 0 2017

Williams Sound Corporation
Mr. Paul Ingebrigtsen
Vice President, Marketing
10399 West 70th Street
Eden Prairie, MN 55344-3459

Re: K970974
Trade/Device Name: Williams Sound, Hearing Personal FM System Model PFM 300/350
Regulation Number: 21 CFR 874.3320
Regulation Name: Group hearing aid or group auditory trainer
Regulatory Class: Class II
Product Code: LZI
Dated: March 11, 1997
Received: March 17, 1997

Dear Mr. Ingebrigtsen:

This letter corrects our substantially equivalent letter of May 2, 1997.

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.

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 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Kesia Alexander

for 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

5.

510(k) Number (if known): 970974

Device Name: HEARING HELPER® PERSONAL FM SYSTEM

Indications For Use: Models PFM300 & PFM350

A. General Indications:

The indications for use of the assistive listening device in this submission is to amplify sound for individuals with impaired hearing. The device is indicated for individuals with hearing loss in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
X 1. Slight	___1. High Frequency - Precipitously Sloping	___1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
___4. Severe	X 4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. FOR IMPROVED SIGNAL TO NOISE RATIO THROUGH PLACEMENT OF A REMOTE MICROPHONE NEAR A DESIRED SOUND SOURCE
2. SEVERE TO PROFOUND LOSS - USED IN CONJUNCTION WITH PERSONAL HEARING AID VIA TELECOIL OR DIRECT AUDIO INPUT.
3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970974

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

Williams Sound®
Helping People Hear

EXHIBIT 3

INDICATION FOR USE:

510(k) Number (if known):

Device Name: WILLIAMS SOUND, HEARING HELPER PERSONAL FM SYSTEM,
Model PFM 300 / PFM 350

Indications for Use:
To improve the signal to noise ratio for a listener in a variety of environments where background noise, poor acoustics, and distance from a desired sound source contribute to hearing difficulty.

Any hearing and speech condition that can be improved by maximizing the signal to noise ratio for the listener. This includes: Low gain amplification for Attention Deficit Disorders, Learning Disabilities, Central Auditory Processing Disorders, amplification for mild to moderate conductive and sensorineural hearing loss, and amplification moderate to severe conductive and sensorineural hearing loss when used in conjunction with a personal hearing aid.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: NA
(Per 21CFR 801.109)

OR

Over the Counter: NA

Optional Format 1-2-96

David A. Lozano
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970974

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