



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

Williams Sound, LLC
c/o Mr. Paul Ingebrigtsen
Vice President, Marketing
10300 Valley View Rd.
Eden Prairie, MN 55344

NOV 16 2012

Re: K970974

Trade/Device Name: Williams Sound, Hearing Personal FM System Model PFM 300/350
Regulation Number:
Regulation Name:
Regulatory Class: Unclassified
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 (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.

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.

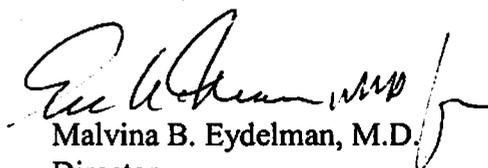
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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



(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K970974