



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Innovia Medical, LLC  
c/o Kevin Walls  
Principal Consultant  
Regulatory Insight, Inc.  
13 Red Fox Lane  
Littleton, CO 80127

MAR 02 2007

Re: K070312  
Trade/Device Name: EarCheck Acoustic Reflectometer  
Regulation Number: 21 CFR 874.1090  
Regulation Name: Auditory Impedance Tester  
Regulatory Class: Class II  
Product Code: ETY  
Dated: January 16, 2007  
Received: February 1, 2007

Dear Mr. Walls:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

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

Indications for Use

510(k) Number (if known): K070312

Device Name: EarCheck Acoustic Reflectometer

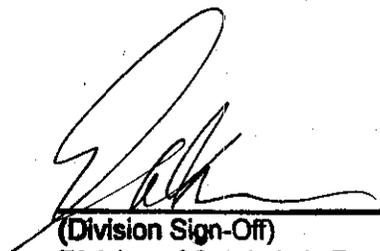
Indications for Use: EarCheck Acoustic Reflectometer is an advanced medical instrument which accurately detects the presence of middle ear fluid (i.e., otitis media with effusion) that may be associated with acute ear infection. The device is intended to assist parents in determining when to seek medical attention. The instrument is designed for use in the home by parents and other caregivers on children from 6 months to young adult.

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use X  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070312

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

Over-the-Counter Use X