K971859

510(k) Summary (as per 21CFR807.92) August 13, 1997

Submitter and Contact Person:

AUG 18 1997

Sandra Kimball
Vice President, Medical and Regulatory Affairs
MDI Instruments, Inc.
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617-935-0150
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Trade Name:

EarCheck

Common Name:

Acoustic Reflectometer

Classification Name:

Auditory Impedance Tester (as per 21CFR874.1090)

Predicate Devices:

MDI EarCheck Pro (K970685)

Description of Device:

EarCheck determines the condition of the middle ear by measuring the response of the ear drum to a sound stimulus. Using a built-in microphone, EarCheck registers the intensity of different frequencies of reflected sound waves to detect the absence or presence of fluid in the middle ear.

The instrument analyzes the mechanical resonance characteristic of the ear drum, indicating the condition of the ear by measuring the Spectral Gradient angle of the ear drum's resonance curve. In a normal ear, the ear drum has full freedom of motion, producing a shallow wide Spectral Gradient angle. When fluid is present, the motion of the ear drum is restricted and a narrower Spectral Gradient angle results. The determination of the absence or presence of middle ear fluid is displayed in one of five levels on the instrument.

Indications for Use:

EarCheck 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.

Summary of Clinical Performance Data:

The EarCheck was tested in both ears of over 500 study subjects in the Validation Study. In summary, the Validation Study demonstrated that the EarCheck can appropriately provide information that indicates a subject's risk of having middle ear effusion (MEE). The Validation Study also demonstrated that the EarCheck was substantially equivalent to the predicate device - the EarCheck Pro - in its performance.

Clinical studies demonstrated statistically significant diagnostic concordance between the EarCheck and the EarCheck Pro.

Furthermore, the Validation Study demonstrated that the diagnostic performance of the EarCheck is consistent with its labeling.

Clinical studies demonstrated that the EarCheck is able to generate reproducible readings on the same ears.

Finally, the Validation Study demonstrated that the EarCheck did not exhibit any actual or potential safety hazards in the testing of both ears, twice in over 500 patients.

Other studies demonstrated that: consumers can take accurate readings, interpret the readings, and take appropriate action; the EarCheck can be appropriately used in the home to monitor middle ear health; the EarCheck performance is comparable to that of the EarCheck Pro and the tympanometer in the presence of earwax; and the EarCheck's human factors design and instructions for use are appropriate.

Technical Specifications:

- Dimensions: 7.0 in, H x 2.75 in, W x 2.5 in, D (169 mm x 87 mm x 87 mm)
- Weight: 6.2 oz (174 g) (With Batteries)
- Measuring Range: 1.8 kHz to 4.4 kHz
- Sound Volume: 80 dB SPL (± 6 dB)
- Sound Duration: 0.2 second sweep
- Display: LCD Display
- Display Hold Time: 10 sec.
- Power: Two AA Alkaline Batteries
- Battery Symbol: Low Battery.
- Battery Life: Approximately 1000 readings in 4 months.
- High Noise Level: Error Indicator.
- Ambient Temperature Operating Range: +50°F to +95°F (15°C to 35°C).

- Relative Humidity Operating Range: <75%
- Storage Temperature Range: -4°F to 122°F (-20°C to +50°C).
- Relative Humidity Storage Range: <85%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 1997

Ms. Sandra Kimball
Vice President, Medical and Regulatory Affairs
MDI Instruments, Inc.
200 Unicorn Park Drive
Woburn, MA 01801

Re: K971859
EarCheck Auditory Impedance Tester
Dated: August 4, 1997
Received: August 7, 1997
Regulatory Class: II
21 CFR 874.1090/Procode: 77 ETY

Dear Ms. Kimball:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971859

Device Name: EarCheck

Indications For Use:

EarCheck 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.

(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 Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971859

Prescription Use ____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)