

MAY 28 1997

## 10.0 510(k) Summary of Safety and Effectiveness for EarCheck Pro

## Indications for Use:

EarCheck Pro 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 instrument is designed for use by doctors and other medical professionals on children from 6 months to young adult.

## Summary of Clinical Performance Data:

The EarCheck Pro was tested in both ears of over 500 study subjects in the Validation Study. In summary, the Validation Study demonstrated that the EarCheck Pro can appropriately provide diagnostic information that indicates a subject's risk of having middle ear effusion (MEE). Sensitivity, specificity, positive predictive value, and negative predictive value calculations demonstrated the EarCheck Pro's ability to appropriately indicate a subject's risk of MEE.

	Sensitivity	Specificity	PPV (20%)	NPV (20%)
EarCheck Pro	0.67	0.87	0.57	0.91

Table 10.1: EarCheck Pro Sensitivity, Specificity, PPV, and NPV

The Validation Study demonstrated that the EarCheck Pro was substantially equivalent to predicate devices - the Acoustic Reflectometer and Tympanometer - in its ability to function as a diagnostic instrument.

Kappa statistic calculations also demonstrated statistically significant diagnostic concordance between the EarCheck Pro and Acoustic Reflectometer, and between the EarCheck Pro and the Tympanometer.

Furthermore, the Validation Study demonstrated that the EarCheck Pro meets or exceeds its diagnostic performance specifications (those specifications being levels of MEE risk associated with various ranges of EarCheck Pro angle readings).

The EarCheck Pro is able to generate reproducible readings on the same ears, as demonstrated by Kappa statistic calculations that showed excellent reproducibility between serial readings.

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

## 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 ( $\pm$  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 3 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%



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K970685  
EarCheck Pro  
Dated: March 31, 1997  
Received: April 3, 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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,

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): K970685

Device Name: EarCheck Pro

Indications for Use:

8.0 Statement of Indications for Use

8.1 Indications For Use

EarCheck Pro 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 instrument is designed for use by doctors and other medical professionals 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)

Prescription Use   
(21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David A. Sigman  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K970685