K073401

MAR 14 2008

510(k) SUMMARY

Company Name and Address:
Micromedics Inc.
1270 Eagan Industrial Road
St. Paul, MN. 55121-1385

Micromedics
Innovative Surgical Products
toll free US: 1-800-624-5662 • *toll free fax:* 1-888-504-0606
local: 651-452-1977 • *local fax:* 651-452-1787
1270 Eagan Industrial Road • St. Paul, MN 55121-1385 USA
www.micromedics.com

Contact Person
Tom Lopac
Manager of Quality & Regulatory Affairs, Micromedics Inc.
Telephone: 651-452-1977
Fax: 651-452-1787

DATE PREPARED: 11-30-07

TRADE NAME: EarPopper
COMMON NAME: Device, inflation, middle ear
PRO CODE: MJV

DESCRIPTION of the DEVICE:

The EarPopper is a non-surgical, non-drug related treatment for middle ear pressure problems such as:

- **Middle ear fluid (Otitis Media with Effusion)**
- **Eustachian Tube Dysfunction**
- **Temporary hearing loss**
- **Ear pain and pressure caused by air travel**
- **Ear fullness caused by colds, allergies, sinusitis**

INDICATIONS FOR USE:

The EarPopper is indicated for the treatment of negative middle ear pressure. Negative middle ear pressure can lead to fluid accumulation in the middle ear, impaired hearing and hearing loss. The EarPopper provides a method of ventilating the middle ear by momentarily increasing the air pressure in the nose and the eustachian tube. Equalizing the pressure can prevent the accumulation of fluid and prevent hearing loss.

SUBSTANTIALLY EQUIVALENT TO:

Earclear (K951596) Arisil Medical
Otovent (K920840) ABIGO Medical Co.
Politzer Bag

K073401

SUMMARY of EQUIVALENCE:

Characteristic Indications	EarPopper	Earclear K951596	Politzer Bag	Otovent K920840
Intended use	The EarPopper is indicated for the treatment of negative middle ear pressure. Negative middle ear pressure can lead to fluid accumulation in the middle ear, impaired hearing and hearing loss. The EarPopper provides a method of ventilating the middle ear by momentarily increasing the air pressure in the nose and the eustachian tube. Equalizing the pressure can prevent the accumulation of fluid and prevent hearing loss.	The Earclear is indicated for the treatment of negative middle ear pressure. Negative middle ear pressure can lead to fluid accumulation in the middle ear, impaired hearing and hearing loss. The Earclear provides a method of ventilating the middle ear by forcing air pressure through the nose and the Eustachian tube into the middle ear. Equalizing the pressure can prevent the accumulation of fluid and prevent hearing loss.	Treatment of negative middle ear pressure	Treatment of negative middle ear pressure
Patient Use	Performed at home by patient on his own, or under adult supervision	Performed at home by patient on his own, or under adult supervision	Performed at home by patient on his own, or under adult supervision, but typically requires a second person to deliver the air pressure	Performed at home by patient on his own, or under adult supervision
Principle of Operation	Ventilating the middle ear by momentarily increasing the air pressure in the nose and the eustachian tube	Ventilation of the middle ear by forcing air under pressure through the nose and the eustachian tube into the middle ear	Ventilation of the middle ear by forcing air under pressure through the nose and the eustachian tube into the middle ear	Ventilation of the middle ear by forcing air under pressure through the nose and the eustachian tube into the middle ear
Mode of Operation	Non-sterile, battery powered device is held against the nostril, delivering continuous air pressure via an air pump	Non-sterile, battery powered device is held against the nostril, delivering continuous air pressure via an air pump	Non-sterile, manual device is held against the nostril, delivering varying amount of air pressure via the compression of a bulb (bag)	Non-sterile, manual device is held against the nostril, delivering varying amount of air pressure via the deflation of the patient-inflated balloon.
Major Components	Plastic (ABS / Polycarbonate / Polystyrene) nosepiece mounted to a plastic case, housing an air pump, batteries and a printed circuit board	Plastic (PVC/ABS/PEI) nosepiece mounted to a plastic case, housing an air pump, batteries and a printed circuit board	Plastic or glass nosepiece mounted to a rubber tube which is connected to a rubber bulb (bag)	Plastic (PVC) nosepiece mounted to a latex balloon
Air Pressure	Continuous, controlled to 3 PSI with air flow of 0.6 L/minute on low setting and 6 PSI with air flow of 1.3 L/minute on high setting.	Continuous, controlled to 1.5 PSI on low setting and 3 PSI on high setting	Varying, uncontrolled range: 1.5 to 5.9 PSI reported by Politzer, 5.2 PSI reported by Schwartz, 10 to 30 PSI reported by Shambaugh	Varying, uncontrolled, value not specified in the product literature

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Micromedics, Inc.
c/o Tom Lopac
Quality Manager
1270 Eagan Industrial Road
Suite 120
St. Paul, MN 55121-1385

MAR 14 2008

Re: K073401
Trade/Device Name: EarPopper
Regulation Number: Unclassified
Product Code: MJV
Dated: February 11, 2008
Received: February 15, 2008

Dear Mr. Lopac:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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.

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

K073401

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): ___K073401_____

Device Name: EarPopper

Indications for Use:

The EarPopper is indicated for the treatment of negative middle ear pressure. Negative middle ear pressure can lead to fluid accumulation in the middle ear, impaired hearing and hearing loss. The EarPopper provides a method of ventilating the middle ear by momentarily increasing the air pressure in the nose and the eustachian tube. Equalizing the pressure can prevent the accumulation of fluid and prevent hearing loss.

Prescription Use: ____X_____ OR Over-The-Counter ___ _____
(Per 21 CFT 801.109)

(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 Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K073401