OCT 2 3 2000

K993094

Non-Confidential Summary of Safety and Effectiveness

MAP
MEDIZINTECHNIK FÜR ARZT UND PATIENT
Germany

Manufacturer	MAP Medizintechnik für Arzt und Patient GmbH & Co. KG Fraunhoferstrasse 16 D-82152 Martinsried Germany
Official Contact	Torsten Schlichtholz, Manager, Quality Management
Proprietary or Trade Name	Aero-Click ®
Common/Usual Name	Passive Exhalation Outlet
Classification Name	Non-Continuous Ventilator
Device	Aero-Click ®
Predicate device	Respironics Whisper Swivel II

Device Description

The Aero-Click ® is a passive exhalation outlet which is placed in the patient circuit between the mask and the air tube of a sleep apnoea therapy device to provide a continuous leak path for the patients exhaled air. It is placed near the patient's face and allows quick connection/disconnection of the mask from the sleep apnoea therapy device.
The device consists of 2 parts which can be easily disconnected. It can be cleaned with dish-washing detergents. Cleaning requires disconnection of the device.
The device can be desinfected with Cidex ®.

Intended Use

Indicated Use	Exhalation outlet for use between masks without openings and air tube of sleep apnoea therapy equipment including quick connector/disconnector capabilities
Targeted Population	Adults
Environment of Use	Home and Hospital
Equipment	Sleep Apnoea Therapy Equipment

Non-Confidential Summary of Safety and Effectiveness
(continued)

Comparison with Predicate Devices		
Attribute	**Aero-Click ®**	**Respironics Whisper Swivel II**
Use		
Intended Use: Breathing circuit passive exhalation port	Yes	Yes
Intended Equipment: CPAP or bi-Level systems	Yes	Yes
Intended environment: Home and Hospital	Yes	Yes
Connector/disconnector capabilities	Yes	No
Design		
Provides continuous flow leak path in circuit	Yes	Yes
Placed close to Patients face	Yes	Yes
Made to be cleaned	Yes	Yes
Provided non-sterile	Yes	Yes
Reusable	Yes	Yes
Materials Polycarbonate Stainless steel	 Yes Yes	 Yes No
Performance Standards/Specifications		
Meets design requirements after cleaning	Yes	Yes

Non-Confidential Summary of Safety and Effectiveness
(continued)

Differences between other legally marketed devices:
The differences between the Whisper Swivel II and the Aero-Click ® are as follows: Use of a stainless steel spring to assure safe connection of both parts of the device instead of polycarbonate. Flow at 100% relative humidity is higher in Aero-Click ® compared to Whisper Swivel II. The 2 parts of the device can be quickly connected/disconnected without removing the mask

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 3 2000

Mr. Torsten Schlichtholz
MAP MEDIZINTECHNIK FUR ARZT UND PATIENT GMBH
FraunhoferstraBe 16
D-82152 Martinsried
GERMANY

Re: K993094
Aero-Click®
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: September 5, 2000
Received: September 11, 2000

Dear Mr. Schlichtholz:

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 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). 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 requirements, 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) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

The following is provided persuant to the Notice of February 6, 1996, regarding Indications for Use

510(k) Number (if known):.	To be assigned
Device Name:	Aero-Click ®
Intended Use:	Exhalation outlet for use between masks without openings and air tube for sleep apnoea therapy including quick connector/disconnector
Target Population:	Adults
Invironment of Use:	Home and Hospital
Equipment for Use:	Sleep Apnoea Therapy Equipment, CPAP and bi-level
Reusable:	Reusable, Multi Use May be disassembled and cleaned Provided non- sterile

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993094