510(k) Summary

[As required by 21 CFR 807.87(h)]

JAN 13 2009

Identification of Submitter

Submitter	Eumedics Medizintechnik und Marketing GmbH Linzer Strasse 45, Purkersdorf, Austria A3002
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Date of Preparation	January 30, 2008
Official Contact Person,	David Levine, President, R1 Technologies LLC 1341 W. Fullerton, 103 Chicago, IL 60614
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Identification of the Product

Device Proprietary Name:	Respifit S
Common Name:	Inspiratory Muscle Trainer
Classification Name:	Spirometer, Therapeutic (incentive)

Marketed Devices to Which Equivalence is Claimed

Device	Manufacturer	510(k) Number
PFLEX RESPIRATORY MUSCLE EXERCISER	Healthscan	K842634
EXPIRATORY BREATHING EXERCISER	DHD Diemolding Healthcare	K945118
THRESHOLD(TM) INSPIRATORY MUSCLE TRAINER	Health Products, Inc.	K870514
MICROLAB SPIROMETER	Micro-Direct, Inc	K031102

Device Description

The Respifit S is a portable device for training the respiratory muscles for strength and endurance.

Indications for Use

a. The Respifit S is indicated for use as a training device and is used for conducting strength and endurance training by inhaling into a patient module. The purpose of this training is to improve inspiratory muscle strength and endurance.
b. The training can be performed in adults and patients with neuromuscular disease and cystic fibrosis in the hospital, clinic and home.

Comparison with Predicate Devices

The Respifit S device is a device that is equivalent to the other inspiratory muscle training devices(K842634, K945118, K870514) in that the patient breathes into a mouthpiece against a resistance. The Respifit S also can store electronically breathing measurements and provide visual feedback in a manner similar to the Microlab Spirometer(K031102) from Micro-Direct. The Respifit S device also provides a measurement of endurance depicted as a form of tidal volume. The Microlab Spirometer (K031102) provides a measurement for tidal volume and endurance training is conducted with the other inspiratory muscle training devices(K842634, K945118, K870514) devices, however these devices do not provide measurable outputs. All tests were verified to meet the required acceptance criteria. In summary, the device described in this submission is substantially equivalent to the predicate devices for the reasons mentioned in this section and the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eumedics Medizintechnik und Marketing GmbH
C/O Mr. Dave Levine
President
R1 Technologies L.L.C.
1341 West Fullerton, Suite 103
Chicago, Illinois 60614

JAN 13 2009

Re: K080299
Trade/Device Name: Respifit S
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: II
Product Code: BWF
Dated: January 8, 2009
Received: January 9, 2009

Dear Mr. Levine:

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) 276-0120. 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,

Ginette Y. Michaud, M.D.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K080299

Device Name: Respifit S

Indications for Use:

The Respifit S is indicated for use as a training device used for conducting strength and endurance training by breathing into a patient module that contains an aperture. The purpose of this training is to improve inspiratory muscle strength and endurance. Training with the Respifit S can be performed in adults and patients with neuromuscular disease and cystic fibrosis in the hospital, clinic and home.

Division Sign-Off

510(k) Number: _____

Prescription Use___X_____ AND/OR Over-The Counter Use_____

(per 21 CFR 801.109 Subpart D) (per 21 CFR 801.109 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080299