K081965

510(k) Summary
(per 21 CFR 807.92(c))

OCT 27 2008

1. Applicant

Tech Avenue Ventures d/b/a MPowRx Health and Wellness Products Inc.
#510 3553-31 St. NW
Calgary, Alberta T2L 2K7
Canada

Contact Person: Gijs van Rooijen, PhD, Principal
Tel: 403-475-8324
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Date Prepared: June 30, 2008

2. Device Name

Trade Name:	MPowRx™ Snoring Solution
Common/Usual Name:	Device, Anti-Snoring
Classification Name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Regulation Number:	872.5570
Product Code:	LRK
Classification:	II
Panel:	Dental

3. Predicate Devices

The MPowRx™ Snoring Solution is substantially equivalent to the following devices:

510(k) Number	Device	Applicant
K954324	Snor-X Mouth Guard	Snorex, Inc.
K993381	Tongue Stabilizer Device	University of Otago
K013687	Nose Breathe Mouthpiece for Heavy Snorer	Steven K. Sue

4. Intended Use

The MPowRx™ Snoring Solution is intended for the treatment of mild to moderate snoring.

5. Description of the Device

The MPowRx™ Snoring Solution is a simple one-piece, one-size-fits-all oral appliance used to prevent mild to moderate snoring. The MPowRx™ Snoring Solution is comfortably retained within the mouth while sleeping.

The MPowRx™ Snoring Solution is fabricated from a common oral appliance material, fits between the lips and teeth, and has an aperture with a protrusion for holding the tongue. Once the protrusion is squeezed to reduce the air volume, a vacuum is formed which keeps the tongue comfortably retained within the protrusion. Forward retention of the tongue helps keep the upper respiratory air passages open to relieve snoring.

6. Safety & Effectiveness

There are no substantial differences between the MPowRx™ Snoring Solution defined in this 510(k) submission and the predicate devices. They have the same indications for use and any differences in technological characteristics do not raise issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 7 2008

MPowRx Health and Wellness Products Incorporated
C/O Ms. Jean Asquith
Senior Regulatory Affairs Consultant
Emergo Group Incorporated
1705 South Capital of Texas Highway, Suite 500
Austin, Texas 78746

Re: K081965
Trade/Device Name: MPowRx™ Snoring Solution
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: October 10, 2008
Received: October 14, 2008

Dear Ms. Asquith:

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.

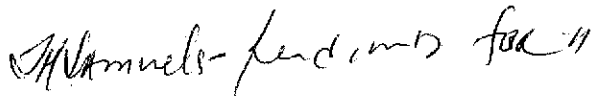
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081965

Indications for Use

510(k) Number (if known): _____

Device Name: MPowRx™ Snoring Solution

Indications for Use:

The MPowRx™ Snoring Solution is intended for the treatment of mild to moderate snoring.

Caution: Federal law restricts this device to sale by or on the order of a physician, dentist or other licensed practitioner.

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)
X		_____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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