K060357

APR 5 2006

PARI 'rek™ S
510(k) Submission
510(k) Summary

Submitt r Information

Name:	PARI Innovative Manufacturers, Inc.
Address	2943 Oak Lake Blvd.
	Midlothian, VA 23112
Phone N mber:	804-253-7274 x269
Fax Nur ber:	804-639-7244
Contact lame:	Michael Judge
Date Pre ared:	December 19, 2005

Device ame

Commo Name:	Nebulizer compressor
Propriet y Name:	PARI Trek™ S
Classific tion Name:	Nebulizer (Direct Patient Interface), 21 CFR 868.5630, Product Code CAF

Legally Marketed Predicate Device(s)

Manufa turer	Device	510(k) Number
PARI In ovative Manufacturers, Inc.	Walkhaler Portable Compressor	K960675
PARI In ovative Manufacturers, Inc.	Proneb® Ultra	K002862

Device escription

The Trel ™ S nebulizer compressor is a portable, DC-powered air compressor intended to provide a source of comp essed air for use with jet nebulizers. The Trek™ S is intended for adult and pediatric patients. The dev e is non-sterile, prescription-use only, intended for use in hospital, clinic, or home environments.

Intende Use

The Tre ™ S nebulizer compressor is a portable, DC-powered air compressor intended to provide a source of comp essed air for use with jet nebulizers. The Trek™ S is intended for adult and pediatric patients.

Techno gical Characteristics Compared to Predicate Device

PARI T k™ S, PARI Proneb® Ultra, and PARI Walkhaler® are all air compressors intended to provide a source o compressed air for use with jet nebulizers. All three devices are piston-driven, oil-free reciproc ting air compressors.

PARI T k™ S employs similar materials compared to the predicate devices, including a polymer cylinder and hou ng, Teflon piston seal and silicon valves. PARI Trek™ S is similar to the Walkhaler® compre or regarding the DC motor, AC-to-DC adapter, and optional battery pack for portable use. Operati g pressure and jet flow produced by the PARI Trek™ S is comparable to the predicates.

Non-Cl ical Test Summary

PARI T k™ S was tested with various nebulizers to compare performance to the predicate devices, includin :

- Tot l Output Rate: PARI Trek™ S TOR is comparable to the predicate devices
- MM D: PARI Trek™ S MMD is comparable to the predicate devices
- Vol me % <5 µm: PARI Trek™ S is comparable to the predicate devices

Clinical Performance Summary

Clinical esting was not completed/is not required to show substantial equivalence.

Conclu ons from Testing

PARI T k™ S meets performance requirements and raises no new issues of safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 2006

Mr. Robert Mosenkis
Citech
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K060357
Trade/Device Name: Trek S
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: March 27, 2006
Received: March 28, 2006

Dear Mr. Mosenkis:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-2022. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Chiu Lin, Ph.D
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): N/A K060357

Device Name: Trek S

Indications for Use:

The Trek S nebulizer compressor is a portable, DC-powered air compressor intended to provide a source of compressed air for use with jet nebulizers. The Trek S is intended for adult and pediatric patients.

Prescription Use XXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

William Tillman

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

K060357

(Posted November 13, 2003)