OCT 0 4 2002

K 022311

Section K

510 (k) Summary

Date Prepared	August 21, 2002
510 (k) no.	
Submitter	RhinoMetrics A/S Industrivej 9, 3540 Lynge Denmark
Contact	Erland Fuglsbjerg, Export Manager or Dan Eggan, Manager of Regulatory Affairs
Device Name	RhinoStream Rhinomanometer
Common/Usual/ Classification name	Rhinoanemometer
Predicate device	Mercury Medical Rhinomanometer
Device description	The RhinoStream Rhinomanometer module is designed to objectively and quickly measure and quantify a dynamic measure of the patient ability breath through the nasal airway passages.
Intended use	The module and its predicate device are intended to be for rhinomanometry measurements and both devices use a manometer probe with pressure transducers to measure the airflow during expiration and inspiration.

Section G

Substantial Equivalency Comparison

Description	Mercury Medical. Rhinomanometer (K) 902120	RhinoStream Rhinomanometer
Device description	**To provide rhinomanometry measurements**	**To provide rhinomanometry measurements**
General indication	To determine the resistance and airflow of the nasal cavity during inspiration and expiration.	**To determine the resistance and airflow of the nasal cavity during inspiration and expiration**
Specific indications	**Diagnosing nasal decongestion, polyps, or enlarged adenoids and evaluating changes in the volume of the nasal passage due to allergies, surgical procedures or medications**	Diagnosing nasal decongestion, polyps, or enlarged adenoids and evaluating changes in the volume of the nasal passage due to allergies, surgical procedures or medications
Technological characteristics	**Utilizes a manometer probe which measures air pressure up to 60 centimeters water pressure**	**Utilizes a manometer probe which measures air pressure up to 5 centimeters water pressure (500 Pa) and air flow up to 1000 ml/s. Although the pressure value is lower than the predicate device, this does not raise concerns as the device measures pressure in relation to the current airflow. A higher pressure would require a higher airflow**
Probe connection	**The probe is handheld and connected to a mask.**	**The probe is connected to a computer with an insulated cable**
Software platform	**No software**	The computer includes Windows 95/98 based software.
Usage	**Challenge comparison**	**Challenge comparison**
Data storage	**Data storage not available.**	**Data storage in ASCI format and Windows 95/98 based software available. Includes an individual patient database and a browser database function for clinical use.**
Print function	Results can not be printed	**Results can be printed and exported to other Windows 95/98 based applications.**
Nose adapter	**No adapters available**	Polystyrene disposable adapter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 4 2002

RhinoMetrics A/S
c/o Daniel Eggan
Manager of Regulatory Affairs/ QA
9675 West 95th Street
Minneapolis, MN 55344

Re: K022311
Trade Name: RhinoStream Rhinomanometer Module
Classification Regulation Number: 868.1800
Regulatory Class: II
Product Code: BXQ
Dated: July 15, 2002
Received: July 17, 2002

Dear Mr. Eggan:

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) 594-4613. 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,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Section A

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: RhinoMetrics A/S

510(k) Number (if known): K022311

Device Name: RhinoStream Rhinomanometer

Indications For Use:

A Rhinomanometer is a medical instrument, intended to measure nasal airway pressure up to 5 centimeters H_2O. (500Pa) and air flow up to 1000 ml/s.
This is a non-invasive procedure, which is useful to the physician in studying the nasal decongestion of the nasal passage as it e.g. changes due to allergies, before and after surgical procedures, responses to medications, presence or absence of polyps, deviated septums, enlarged adenoids, etc.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K022311