K062155

510(k) Summary
for
Digital MXR-D Flowmeter

NOV - 9 2006

1. SPONSOR

Parker Hannifin Corporation
Porter Instrument Division
245 Township Line Rd.
P.O. Box 907
Hatfield, PA 19440-0907

Contact Person: Stephen Loeffler
Telephone: 215-723-4000

Date Prepared October 17, 2006

2. DEVICE NAME

Proprietary Name: Digital MXR-D Flowmeter
Common/Usual Name: Flowmeter
Classification Name: Analgesia gas machine

3. PREDICATE DEVICES

- Porter Instrument Co. MXR 2000 Flowmeter (K923781)
- Digital Ultra Analgesia Gas Machine (K052335)
- Matrx Digital MDM™, RA (K945722)

4. DEVICE DESCRIPTION

The proposed Digital MXR-D Flowmeter is a modification of the MXR 2000 Flowmeter that was cleared for marketing in the U.S. as K923781. The major modification to the MXR 2000 Flowmeter to produce the proposed Digital MXR-D Flowmeter is the addition of an electronically controlled digital display to the control panel of the cabinet mount version. The electronics incorporated in the Digital MXR-D Flowmeter function as follows:

- Turn flow and electronics on/off and display start-up information

- Display nitrous oxide (N_2O) percentage and total flow
- Display information and instructions (i.e. fault conditions and error codes)
- Provide an audible signal for certain fault conditions.

5. INTENDED USE

The Digital MXR-D Flowmeter is intended for use in nitrous oxide/oxygen sedation systems for the delivery of a mixture of nitrous oxide and oxygen gases where the maximum nitrous oxide concentration is 70%.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Digital MXR-D Flowmeter and the predicate Digital Ultra Analgesia Gas Machine and the Matrx Digital MDM™, RA all incorporate a control panel that includes a digital display for setting device parameters – including flow rate and concentration. The major difference between the proposed Digital MXR-D Flowmeter and the predicate Digital Ultra Analgesia Gas Machine and the Matrx Digital MDM™, RA devices is that these predicate devices provide electronic control of flow rate and concentration from the control panel.

The modifications to the predicate MXR 2000 Flowmeter that was implemented to produce the proposed Digital MXR-D Flowmeter is limited to the addition of the necessary hardware and software to support a digital display with the features identified in the bulleted list (see Section 4 of this summary). The proposed modification does **not** include electronic control of N_2O percentage and flow rate. Like the predicate MXR 2000 Flowmeter, control of N_2O percentage and total flow rate is mechanical in the proposed device, using the control knobs on the front of the Control Panel.

7. PERFORMANCE TESTING

Testing conducted to evaluate the functional performance and safety of the proposed Digital MXR-D Flowmeter includes software and hardware verification and validation and electrical safety and electromagnetic compatibility. The test results confirm that the proposed Digital MXR-D Flowmeter performs within established specifications and is safe and effective for use as a dental analgesia gas machine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Porter Instrument Company, Limited
C/O Cynthia J. M. Nolte, Ph.D., RAC
Senior Staff Consultant
Medical Device Consultant, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

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Re: K062155
Trade/Device Name: Digital MXR-D Flowmeter
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: October 17, 2006
Received: October 18, 2006

Dear Dr. Nolte:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 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

510(k) Number (if known): K062155

Device Name: Digital MXR-D Flowmeter

Indications For Use:

The Digital MXR-D Flowmeter is intended for use in nitrous oxide/oxygen sedation systems for the delivery of a mixture of nitrous oxide and oxygen gases where the maximum nitrous oxide concentration is 70%.

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sophie Y. Michaud DMD

of Anaesthesiology, General Hospital,
ion Control, Dental Devices

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