K080039

APR 14 2008

510(k) Summary:

The Passive Waste Gas Scavenger is intended to be used for the scavenging of waste anesthetic gases from anesthesia machines used during the provision of general anesthesia to adults and children. The device meets the criteria for an active waste gas scavenger in the event the environment changes during use and negative pressure enters the evacuation system.

Submitter:

G. Dundas Company, Inc.
24301 Roberts Drive
Black Diamond, WA 98010
253-631-8008 (phone)
360-886-1350 (fax)

Contact:

Mario Sorci

Date:

2 January, 2008

Device Name:

Passive Waste Gas Scavenger

Classification Name:

Apparatus, Gas Scavenging

Product Code:

CBN

Regulation Number:

868.5430

Predicate Devices:

K842003
Ohio Waste Gas Scavenging Interface
Applicant: Ohio Medical Products

K790333
NAD Scavenging Relief Valve
Applicant: Drager Medical, Inc.

Device Description:

The Passive Waste Gas Scavenger is intended to be used for the scavenging of waste anesthetic gases from anesthesia machines used during the provision of general anesthesia to adults and children. The Passive Waste Gas Scavenger is designed for use with non-recirculating waste gas disposal systems and is intended for prescription use only. This scavenging approach relies on the pressure of the waste gas to transfer the gas from the scavenger to the exhaust system.

The scavenger body incorporates one 30mm/27mm/19mm horizontal hose terminal to connect the scavenger to the anesthesia machine. The vertically oriented 30mm/19mm hose terminal is intended to connect the scavenger to the exhaust system.

The G. Dundas Passive Scavenger incorporates the same safety systems as predicate devices, providing relief of excess positive pressure and excess negative pressure to the patient through the use of pressure relief valves, in compliance with ASTM 1343-02 – Anesthetic Equipment – Scavenging Systems for Anesthetic Gases. Although there is no standard for passive waste gas scavenging systems, the G. Dundas Passive Scavenger is designed to fail safe under active waste disposal conditions.

The G. Dundas Passive Scavenger and the predicate devices were tested and found to have similar performance. Testing procedures and data can be found in Section 7 of this application.

3.a. Regulation CBN, Product Code 868.5430

3.b. Principle of Operation: The 14600 Passive Waste Gas Scavenger is intended to be used for the scavenging of waste anesthetic gases from anesthesia machines used during the provision of general anesthesia. It is designed for use with non-recirculating waste gas disposal systems. This scavenging approach relies on the pressure of the waste gas to transfer the gas from the scavenger to the exhaust system. The 14600 is not designed for patient contact and is a reusable device.

The inlet port is attached to the ventilation system of the anesthesia machine. During operation, waste gases from the patient are transfer into the scavenger by the outlet pressure supplied by the ventilator. The gases will then travel through the scavenger into a non-recirculating exhaust system. Under normal operating conditions (75 L/min flow through the inlet), the pressure shall not exceed 3.0 cm H_2O.

The 14600 is designed with fault tolerances to handle changes in conditions of both the ventilator and the exhaust system. If pressure increases due to exit port occlusion or a blockage in the exhaust system, the positive pressure relief valve will open, limiting the inlet pressure to less than or equal to 9 cm H_2O. If conditions allow the exhaust system to become an active take away system, the negative relief valve will open, not allowing the inlet pressure to go below -2.5 mm H_2O.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2008

Mr. Mario Sorci
G. Dundas Company, Incorporated
24301 Roberts Drive
Black Diamond, Washington 98010

Re: K080039
Trade/Device Name: Passive Waste Gas Scavenger
Regulation Number: 21 CFR 868.5430
Regulation Name: Gas-Scavenging Apparatus
Regulatory Class: II
Product Code: CBN
Dated: January 3, 2008
Received: March 31, 2008

Dear Mr. Sorci:

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) 276-0115. 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 (301) 443-6597 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

Statement of Indication for Use:

510(k) Number:

Device Name: Passive Waste Gas Scavenger

The Passive Waste Gas Scavenger is intended to be used for the scavenging of waste anesthetic gases from anesthesia machines used during the provision of general anesthesia to adults and children. The Passive Waste Gas Scavenger is designed for use with non-recirculating waste gas disposal systems and is intended for prescription use only.

Prescription Use __X___ And/Or Over the Counter Use ____.
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anita Y. Mahan DMD

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

510(k) Number: K080039