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K080175

510(k) Summary
Navigator Anesthesia Delivery System

JUN - 9 2008

This 510(K) Summary is provided in accordance with 21 CFR 807.92.

Date: January 23, 2008

Submitter:

Datascope Corp.
800 MacArthur Blvd.
Mahwah, NJ 07430
Contact: Kathleen Kramer
Manager, Clinical and Regulatory Affairs
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Device Trade Name: Navigator Anesthesia Delivery System

Common Name: Gas-Machine, Anesthesia

Device Classification: Anesthesiology
21 CFR 868.5160, Product code: BSZ, Class: II

Predicate Devices: Modular Anesthesia System, Heyer America Inc. (K001988) and Avance Anesthesia System, GE Datex-Ohmeda (K071142).

Device description: The Navigator Anesthesia Delivery System is a continuous flow anesthesia system which offers manual or automatic ventilation, easily adjustable fresh gas delivery, anesthetic agent delivery, ventilation monitoring, convenient ergonomics, and state-of-the-art safety systems. The Navigator System is designed to decrease the risk of hypoxic mixtures and the inadvertent movement of the air flow control knobs. Additionally, the Navigator provides battery power in the event of an AC power outage.

Multiple ventilation modes, i.e., CMV, PCV, SIMV and PSV, are offered by the Navigator System with electronic PEEP available in each of the modes. The fresh gas dosing subsystem offers features of a traditional anesthesia system along with dual flow tubes which display the gas flows at all times. The Navigator contains two vaporizers and a heated breathing system to minimize condensation and return moisture to the patient.

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Indications for Use:

The Navigator Anesthesia Delivery System is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation.

The Navigator System is intended for use by licensed clinicians, for patient requiring anesthesia within a health care facility, and can be used in both adult and pediatric populations.

Technological Comparison to Predicate Device:

The Navigator System is technically equivalent to Heyer America's Modular Anesthesia System (K001988) and GE Datex-Ohmeda's Avance Anesthesia System (K071142) with respect to indications for use and technical/performance characteristics.

Summary of Performance Testing:

The Navigator System has been tested and found to be in compliance with recognized safety, performance and electromagnetic compatibility standards.

A risk analysis has been developed to identify potential hazards and document the mitigation of the hazards. The device's software has been validated in accordance with the requirements set forth in the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

Conclusion:

Based on the above description, technological comparison, performance testing and the supporting documentation it can be concluded that the Navigator Anesthesia Delivery System is safe, effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kathleen Kramer
Manager, Clinical & Regulatory Affairs
Datascope Corporation
Patient Monitoring Division
800 MacArthur Boulevard
Mahwah, New Jersey 07430

JUN - 9 2008

Re: K080175
Trade/Device Name: Navigator Anesthesia Delivery System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: May 16, 2008
Received: May 19, 2008

Dear Ms. Kramer:

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

Indications for Use

510(k) Number (if known):

Device Name: Navigator Anesthesia Delivery System

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K080175