



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 12 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Datascope Corp.
c/o Ms. Susan E. Mandy
Director, Clinical and Regulatory Affairs
800 MacArthur Blvd.
Mahwah, NJ 07430

Re: K051897
Trade Name: Trio Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Monitor, Physiologic, Patient (without Arrhythmia)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: July 12, 2005
Received: July 13, 2005

Dear Ms. Mandy,

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.

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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 (301) 594-4646. 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/dsma/dsmamain.html>

Sincerely yours,



Brian D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K051897

Device Name: Trio Monitor

Indications for Use:

INDICATION FOR USE STATEMENT

The Trio™ monitor is intended for use in healthcare settings under the direct supervision of a licensed healthcare practitioner. The intended use of the monitor is to monitor physiologic parameter data on adult and pediatric patients. Physiologic data includes: electrocardiogram, invasive blood pressure, non-invasive blood pressure (NIBP), pulse oximetry, heart rate (derived from ECG, SpO₂ or NIBP), respiration and temperature as summarized in the operating instructions manual. The information can be displayed, stored, trended and printed.

The monitor is not intended for home use. The monitor is not intended to be an apnea monitor. It was not designed or validated for use as an apnea monitor

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 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051897