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510(k) Summary of Safety and Effectiveness

Date: July 22, 2003

Submitter: Patient Monitoring Division
Datascope Corp.

Contact Person: Susan E. Mandy
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Patient Monitoring Division
Datascope Corp.
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Device trade name: Trio Monitor

Common/usual name: Physiological Patient Monitor

Classification name:

21 CFR 870.1100	Blood pressure alarm
21 CFR 870.1130	Noninvasive blood pressure measurement systems
21 CFR 870.1110	Blood pressure computer
21 CFR 870.2300	Cardiac monitor (including cardiotachometer and rate alarm)
21 CFR 870.2340	Electrocardiograph
21 CFR 870.2700	Oximeter
21 CFR 880.2910	Clinical electronic thermometers

Predicate Device: GE Medical Systems Dash 2000 Pro Patient Monitor

Device Description: Mindray Bio-Medical Co. Ltd., previously known as Caymans Mindray Medical Electronic Company of Shenzen, China, manufactures the Trio monitor for Datascope Corp.

The Trio monitor is a three or four trace patient monitor that can be mounted on a rolling stand, wall mount bracket, bed rail, or operated as a tabletop device. The patient parameters that can be monitored on the Trio are: ECG (3-lead or 5- lead selectable), Temperature, SpO2, Invasive Blood Pressure, Respiration and Non-Invasive Blood Pressure. Digital displays are provided for Heart Rate, Pulse Rate, Pulse Oximetry, Non-Invasive Blood Pressure, Respiration Rate, Invasive Blood Pressure (optional) and Temperature. Waveform displays are provided for ECG, Pleth, Invasive Blood Pressure (optional) and Respiration. The optional

built-in thermal recorder provides hard copies of all digital data and waveforms, as well as Tabular and Graphic Trend information.

Intended Use: The Trio monitor is intended for hospital use 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 but is not restricted to: electrocardiogram, invasive blood pressure, heart rate (derived from ECG and SpO2) noninvasive blood pressure, pulse oximetry, respiration and temperature as summarized in the operating instructions manual. The information can be displayed, stored, trended and printed.

Technology: The Trio monitor employs the same functional technology as the predicate device.

Test Summary The Trio monitor complies with the voluntary standards identified in section six of this submission. During the development process of the Trio monitor, the following activities were completed:

- Requirements specification review
- Hardware and software testing
- Code design and code reviews
- Environmental testing
- Safety testing
- Performance testing
- Risk Analysis
- Hardware and Software validation

Conclusion The results of these measurements demonstrated that the Trio monitor is as safe, as effective and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2004

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

Re: K032338
Trade Name: Trio™ Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: December 23, 2003
Received: December 24, 2003

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.

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 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032338

Device Name: Trio Monitor

Indications For Use:

INDICATION FOR USE STATEMENT

The Trio™ monitor is intended for hospital use 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, noninvasive blood pressure, pulse oximetry, heart rate (derived from ECG or SpO_2), 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___ (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)

Donna R. Vachuel

(Division Sign-Off)
Division of Cardiovascular Devices

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