AUG 2 8 2002

K020530

510(k) Summary
Datascope Passport 2® Vital Signs Monitor with View 12™ ECG Analysis Module

Submitter:

Datascope Corp.
Patient Monitoring Division
800 MacArthur Boulevard
Mahwah, New Jersey 07430-0619
Tel: (201) 995-8391
Fax: (201) 995-8605

- **Contact Person:**

Russell Olsen
Director, Quality and Regulatory Affairs
Datascope Corp.
Patient Monitoring Division
Tel: (201) 995-8391
Fax: (201) 995-8605
Email: russell_olsen@datascope.com

- **Date Prepared:** February 5, 2002

Name of the device:

- Trade/Proprietary Name: Passport 2® Vital Signs Monitor with View 12™ ECG Analysis Module

Please note that during the product development process, the device was also referred to as "Passport 2 12-lead", and the Passport 2 Vital Signs Monitor was also referred as "Enterprise" and "Enterprise Configured Monitor" (or "ECM"). These names will be found in some of the supporting documentation included in this submission.

- Common Name: Multi-parameter patient monitoring system

- Classification:

21 CFR 870.1025	Arrhythmia detector and alarm	74 DSI	Class III

Legally Marketed Predicate Devices:

The View 12 ECG Analysis Module is an addition to the existing Passport 2 Vital Signs Monitor (K993531). This submission compares the performance specifications and functionality of the Passport 2 Vital Signs Monitor with View 12 ECG Analysis Module to those of the Spacelabs Ultraview 1050 Monitor (K972282) equipped with Integrated Multiparameter Module 90496 (K972502). The functionality of the Passport 2 Vital Signs monitor with View 12 ECG Analysis Module is identical to that of the Spacelabs Ultraview 1050 monitor equipped with Integrated Multiparameter Module 90496.
In addition, the diagnostic ECG algorithm used in Datascope's View 12 ECG Analysis Module is identical to that found in the Spacelabs Integrated Multiparameter Module 90496, as well as in the Mortara Instrument ELI-100 (K920627), ELI-200 (K920626A) and ELI-300 (K933143).

Description:

The View 12 ECG Analysis Module provides means for performing diagnostic ECG analysis in conjunction with the monitoring functions of Datascope's Passport 2 Vital Signs Monitor (K993531). The View 12 ECG Analysis Module for the Passport 2 Vital Signs Monitor enables 12-Lead ECG Acquisition, Continuous 12-Lead ST Segment Analysis and Arrhythmia Analysis all with print capabilities. The View 12 ECG Analysis Module consists of a PCMCIA ECG processor card that interfaces with the Passport 2, a front-end electronics cable, and a detachable patient cable with integral leadwire set. The data acquired by this module is interpreted utilizing Mortara Instrument's algorithm (cleared by FDA under notification numbers: K920627, K920626A and K933143) for interpretive electrocardiographs. With the View 12 ECG Analysis Module installed and enabled, the Passport 2 makes interpretive statements on printouts. These statements are categorized into three (3) sections: an interpretive statement, a condition statement, and a rhythm statement.

Statement of Intended Use:

In addition to the indications for use identified for the Passport 2 Vital Signs Monitor (K993531), the indications for use for the Passport 2 equipped with the View 12 ECG Analysis Module include the monitoring of the ECG waveform derived from 12 lead measurements, 12 lead ST Segment Analysis, 12 lead Ventricular Arrhythmia Detection and Interpretation of Resting 12 lead ECG.
The target populations are adult, pediatric and neonate, with the exceptions of the:

- Ventricular Arrhythmia Detection and ST Segment Analysis functions, for which the target populations are adult and pediatric only, and
- Interpretation of Resting 12 lead ECG, for which the target population is adult only.

The monitor is intended for use in the health care facility setting. It is intended for use by qualified medical personnel trained in the use of the equipment.
The monitor is not recommended for use in a patient's home or residence, during patient transport other than intra-hospital, or when it has not been ordered by a physician.

Comparison of Technological Characteristics

The Passport 2 Vital Signs monitor with View 12 ECG Analysis Module is substantially equivalent to Spacelabs Medical Ultraview 1050 Monitor with Integrated Multiparameter Module 90496. The diagnostic ECG algorithm used in Datascope's View 12 ECG Analysis Module is identical to that found in the Spacelabs' Integrated Multiparameter Module 90496, as well as in the Mortara Instrument ELI-100 (K920627), ELI-200 (K920626A) and ELI-300 (K933143.) The design, components, storage technology and energy source of the Passport 2 are similar to those of its predicate device.

Testing:

The Passport 2 Vital Signs monitor with View 12 ECG Analysis Module has been subjected to extensive safety and performance testing. Final testing for the monitor equipped with the View 12 ECG Analysis Module included various performance tests designed to ensure that the device meets all functional requirements and performance specifications. Certain safety testing has been performed by third party agencies to ensure the device complies with applicable industry and safety standards. The Passport 2 Vital Signs monitor with View 12 ECG Analysis Module has also been tested to assure compliance with the requirements of various published standards, including ANSI/AAMI EC11 and EC 13, IEC 60601-1 (1988-12) with Amendment 1 (1991-11) & Amendment 2 (1995-03), IEC 60601-1-1 (1992-06) with Amendment 1 (1995-11), IEC 60601-1-2 (1993-04), IEC 60601-1-4 (1996-05), IEC 60601-2-25:1993, ISO 10993-1 (1997), and EN 1441 (1997).

In conclusion, the Passport 2 Vital Signs monitor with View 12 ECG Analysis Module is substantially equivalent to the predicate devices and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2002

Datascope Corporation
c/o Mr. Russell Olsen
Director, Quality and Regulatory Affairs
Patient Monitoring Division
800 MacArthur Blvd.
Mahwah, NJ 07430-0619

Re: K020550
Trade Name: Passport 2® with View 12™ ECG Analysis Module
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: DSI
Dated: June 6, 2002
Received: June 7, 2002

Dear Mr. Olsen:

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.

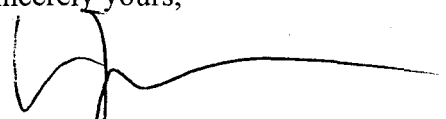
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

INDICATION FOR USE STATEMENT

The indications for use for the Passport 2® with View 12™ ECG Analysis Module include the monitoring of the following human physiological parameters:

- ECG waveform derived from 3, 5 or 12 lead measurements
  Heart Rate derived from selected sources (SpO_2 , ECG, IBP, NIBP)
- Blood Oxygenation (SpO_2)* measurement/waveform
- ST Segment Analysis derived from 5 or 12 lead measurements
- Lethal Arrhythmia Detection derived from 5 or 12 lead measurements
  Non Invasive Blood Pressure (NIBP) measurement
  Invasive Blood Pressure (IBP) measurement/waveform measurable at two sites
  Respiration Rate/ waveform derived from ECG or CO_2
- CO_2 , Inspired and end tidal microstream/waveform
  Temperature measurement via YSI 400/700 series probes
- Interpretation of Resting 12 lead ECG

The target populations are adult, pediatric and neonate with the exception of the:

- Lethal Arrhythmia Detection and ST Segment Analysis, for which the target populations are adult and pediatric only, and
- Interpretation of Resting 12 Lead ECG, for which the target population is adult only.

The monitor is intended for use in the health care facility setting.

The device has the capability of interfacing with Datascope's Gas Module II, displaying the measurements of Anesthetic Gases, O_2, N_2O, and CO_2.

* The device monitors the SpO_2 parameter via the Masimo SET® 2000 Pulse Oximeter Technology and Accessories (K990966). The Masimo SET® 2000 Pulse Oximeter Technology and Accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) and are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

Prescription Use ✓

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K020550