JAN 1 3 2000

K993531

510(k) Summary

Datascope Passport 2™ Vital Signs Monitor

Submitter: Datascope Corp.
Patient Monitoring Division
580 Winters Avenue
Paramus, NJ 07652
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Patient Monitoring Division
580 Winters Avenue
Paramus, NJ 07652
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- **Date Prepared:** October 15, 1999

Name of the device:

- Trade/Proprietary Name: Passport 2™ Vital Signs Monitor

Please note that during the product development process, the device was also referred to as "Enterprise" and "Enterprise Configured Monitor" (or "ECM") and 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
21 CFR 870.1110	Blood Pressure computer	74 CAA	Class II
21 CFR 870.1130	Noninvasive blood pressure measurement System	74 BXD	Class II
21 CFR 868.1400	Analyzer, Gas,Carbon-Dioxide, Gaseous-Phase	73 CCK	Class II
21 CFR 880.2910	Monitor, Temperature (with probe)	80 BWX	Class II
21 CFR 870.2300	Cardiac Monitor (Incl. Cardiotachometer and rate alarm)	74 DRT	Class II
21 CFR 870.2700	Oximeter	74 BWS	Class II

Legally Marketed Predicate Devices:

This submission compares the performance specifications and functionality of the Passport 2 Vital Signs Monitor with those of several similar devices: the Spacelabs Ultraview 1050 Monitor (K972282 & K972502), Marquette Eagle 3000/3100 monitor (K961139, K960272 & K960418), and Datascope Passport 5L-CE Vital Signs monitor (K974178). The functionality of the Passport 2 Vital Signs monitor is identical to that of the Spacelabs Ultraview 1050 monitor and Marquette Eagle 3000/3100 monitor.

In addition, several functions of the Passport 2 employ technology incorporated into previously cleared devices, and several modules or other devices that may be connected to the Passport 2 have received separate clearances from the Agency, as follows:

1. The NIBP measurement system used in the Passport 2 is the same as that used in Datascope's Accutorr Plus NIBP monitor, cleared under 510(k) Notification K983575.
2. The SpO_2 measurement system used in the Passport 2 is the same as that used in the Masimo SET 2000 Pulse Oximeter, cleared under 510(k) Notification K974903.
3. The optional MediCO_2 Microstream CO_2 module was cleared under 510(k) Notification K964239.
4. The optional Datascope Gas Module II, to which the Passport 2 can be connected, was cleared under 510(k) Notification K974903.
5. Datascope's Visa Central Station monitor, to which the Passport 2 can be connected, was cleared under 510(k) Notification K913576.
6. Datascope's Defibrillator, to which the Passport 2 can be connected, was cleared under 510(k) Notification K930548.

Description:

Passport 2 is a transportable, multi-parameter physiological monitor designed to monitor ECG, Heart Rate derived from selected source (SpO_2, ECG, IBP and NIBP), SpO_2 level, ST Segment (adult and pediatric only), Arrhythmia (adult and pediatric only), Blood Pressure (both Invasive and Non-Invasive), Respiration Rate (derived from ECG or CO_2), CO_2 and Temperature, and for adult, pediatric, and neonatal patients who are under the care of a physician, within the confines of a health care facility.

The Passport 2 can display measurements of five Anesthetic Gases (Halothane, Enflurane, Isoflurane, Sevoflurane, and Desflurane), O_2, N_2O, and CO_2 via connection to the stand alone Gas Module II (K974903). The optional MediCO_2 Microstream™ CO_2 module (K964239), which uses the Oridion Microstream™ CO_2, provides EtCO_2, FiCO_2 and Respiration Rate monitoring.

The optional built-in recorder provides hard copies of all digital data and waveforms as well as Tabular & Graphic Trend Information. Through its Comm Port the Passport 2 can communicate with the Visa Central Station (K913576), Gas Module II (K974903), Defibrillator (K930548), a Hospital's Nurse Call System or a Remote Color Display.

Statement of Intended Use:

The Passport 2 Vital Signs monitor is designed to monitor and display the following physiological parameter: ECG, Heart Rate derived from selected sources (SpO_2, ECG, IBP and NIBP), SpO_2 level, ST Segment, Arrhythmia, Blood Pressure (both Invasive and Non-Invasive), Respiration Rate (derived from ECG or CO_2), inspired or expired CO_2, Temperature, and Gases (i.e., Five Anesthetic Gases, O_2, N_2O, and CO_2). Its design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs.

The target populations are adult, pediatric and neonate, with the exception of the Lethal Arrhythmia Detection and ST Segment Analysis functions for which the target populations are adult and pediatric only.

The monitor is intended for use in the health care facility setting. It is intended for use by physicians, physician assistants, registered nurses, certified registered nurse, anesthetists, or other hospital personnel trained in the use of the equipment.

The Passport 2 Vital Signs 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 is substantially equivalent to a combination of systems currently marketed by Spacelabs Medical, Marquette, and Datascope Corp. The design, components, storage technology and energy source of the Passport 2 are similar to those of its predicate devices. All these systems provide a means for interfacing with a patient, collecting parameter specific physiological data, and processing the data for alarm generation and display of numeric values and waveforms on a bedside or central monitoring system. There is only one notable difference between the technical specifications of the Passport 2 Vital Signs monitor and those of the three comparable systems described above. This difference relates to the Passport 2's measurement range for Systolic and Diastolic Pressure in the Pediatric Mode. In this instance, however, the specifications of the Passport 2 are identical to those of another previously cleared device, as the Passport 2 uses the NIBP algorithm from the Accutorr Plus Non Invasive Blood Pressure Monitor (K983575). Therefore, the NIBP function of the Passport 2 is substantially equivalent to the NIBP function of a previously cleared device.

Testing:

The Passport 2 Vital Signs monitor has been subject to extensive safety and performance testing. Final testing for the monitor included various performance tests designed to ensure that the device meets all functional requirements and performance specifications. Some safety testing has been performed by third party agencies to ensure the device complies to applicable industry and safety standards. The Passport 2 Vital Signs monitor has also been tested to assure compliance to the requirements of various published standards, including ANSI/AAMI EC13 and EC 11, AAMI ECAR-1987, EN 864-1997, EN 865-1997, ANSI/AAMI SP-10, 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 60601-2-27, IEC 60601-2-30, and EN 1441 (1997).

In conclusion, the Passport 2 Vital Signs monitor 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

JAN 13 2000

Russell Olsen
Director, Quality and Regulatory Affairs
Datascope Corporation
Patient Monitoring Division
580 Winters Avenue
Paramus, NJ 07652

Re: K993531
Passport 2 Vital Signs Monitor
Regulatory Class: III (three)
Product Code: DSI
Dated: October 16, 1999
Received: October 18, 1999

Dear Mr. Olsen:

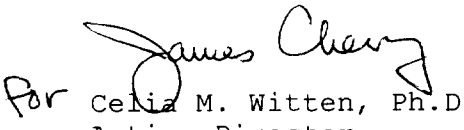
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



For Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

The indications for use for the Passport 2™ include the monitoring of the following human physiological parameters:

- ECG waveform derived from 3 or 5 lead measurements
- Heart Rate derived from selected sources (SpO_2 , ECG, IBP, NIBP)
- Blood Oxygenation (SpO_2)* measurement/waveform
- ST Segment Analysis
- Lethal Arrhythmia Detection
- 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 mainstream/waveform
- Temperature measurement via YSI 400/700 series probes

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

The Passport 2 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 Passport 2 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.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K993531