Attachment A K083821

510（K）Summary of Safety and Effectiveness

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

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MAY 14 2009

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Proprietary Name: Vital Signs Monitor (Model M3B)

Classification Name: 21 CFR 870.2700 Oximeter DQA

21 CFR 868.1400 analyzer, gas, carbon-dioxide, gaseous-p CCK

Predicate Devices:

Predicate devices	Capnostream 20	TidalWave SP, Model 710/715
Manufacturer	Oridion 1987 Medical Ltd	Respironics ovametrix, Incorporated
K #	K060065	K032971

Device Description: M3B Vital Signs Monitor supplies the following features:

- 5.7 inch LCD display
- SpO2, Pulse Rate, and Respironics CO2 measurement
- Nellcor OxiMax SpO2
- Display numeric and waveform information simultaneously
- Nurse call
- Powerful storage capacity
- Built-in Lithium-ion Battery
- Suitable for adult, pediatric and neonate patients
- Visual and audible alarm

Comparison with predicate device

Attachment A

Monitoring functions	M3B Vital Signs Monitor	Capnostream 20	TidalWave SP, Model 710/715
SpO2, Pulse Rate	yes	yes	yes
CO2 measurement	yes	yes	yes

Intended Use:

The Vital Signs Monitor is indicated for use for non-invasive continuous monitoring of oxygen saturation of the blood (SpO2) and CO2.

The Vital Signs Monitor is intended to be used only under regular supervision of clinical personnel. It is adaptable to adult, pediatric, and neonatal usage in a hospital, hospital type facilities environment and intra-hospital moves.

The Vital Signs Monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

Test Summary:

The following quality assurance measures were applied to the development of the Fetal & Maternal Monitor

- Software testing
- Safety testing
- Risk analysis
- Final validation

Conclusion:

Verification and validation testing was done on the M3B Vital Signs Monitor. This premarket notification submission demonstrates that M3B Vital Signs Monitor is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2009

Edan Instruments, Incorporated
C/o Mr. William Stern
Multigon Industries, Incorporated
1 Odell Plaza
Yonkers, New York 10701

Re: K083821
Trade/Device Name: Vital Signs Monitor (Model M3B)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, CCK
Dated: May 5, 2009
Received: May 6, 2009

Dear Mr. Stern:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment A

Indication for Use

510(k) Number (if known): K083821

Device Name: Vital Signs Monitor (Model M3B)

The Vital Signs Monitor is indicated for use for non-invasive continuous monitoring of oxygen saturation of the blood (SpO2) and CO2.

The Vital Signs Monitor is intended to be used only under regular supervision of clinical personnel. It is adaptable to adult, pediatric, and neonatal usage in a hospital environment and intra-hospital moves.

The Vital Signs Monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

Prescription Use _X_ Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

510(k) Number: K083821