K083063

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DEC 1 6 2008

Traditional 510(k): Device Modification – VitaLogik Patient Monitor - BIS

Terminology

VitaLogik = Subject of this 510(k). The VitaLogik Patient Monitor is a modified device, a system identical to the VitaLogik Patient Monitor with the addition of BISx Interface.
The VitaLogik 5X00 was clearded by the FDA on 20th Dec, 2005 K052288
The VitaLogik 4X00 was cleared by the FDA on 21th Nov, 2007 K073140

BIS module of the Envoy monitor– The predicate device. The addition of the BIS Module to the Envoy Patient Monitor was cleared by the FDA at Oct. 2007 K071899

Intended Use of the VitaLogik Patient Monitor

The VitaLogik Monitor is a physiological patient monitor intended to be used for monitoring vital signs of critically ill adult and pediatric patients in the hospital environment, such as: ECG/Heart Rate, Invasive Blood Pressure, Respiration, Temperature, Noninvasive Blood Pressure, CO, Pulse Oximetry, $EtCO_2$ and BIS. The VitaLogik may be used to monitor a wide range of patient conditions in many different clinical specialties within the hospital. The device is intended for use by qualified health care providers, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

Indications for use – VitaLogik with BIS Interface

VitaLogik series is intended for use as a multiparameter physiological patient monitoring system. The VitaLogik series can monitor ECG/heart rate, invasive blood pressure channels, temperature channels, pulse oximetry, respiration, non-invasive blood pressure and EtCO2. This effectively allows the VitaLogik series to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.
Functions include display of multiparameter waveforms, vital signs, alarm & status messages. The Mennen Medical VitaLogik is intended for sale as a system for monitoring and recording patient information or any in-hospital application requiring patient monitoring.

The following are examples of intended clinical applications:

- Critical Care Patients
- Cardiac Step-down/Telemetry Units
- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

BIS - Indication for use

The Mennen Medical VitaLogik BIS interface

is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS Index, a processed parameter may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

- The Bispectral Index is a complex technology, intended for use only as an adjunct to clinical judgment and training.
- In addition, the clinical utility, risk/benefit, and application of this device have not undergone full evaluation in the pediatric population.

*The Intended Use of the VitaLogik monitor as indicated above are same as the Indications For Use.

Device Description – VitaLogik Patient Monitor with BIS Interface

The VitaLogik is a multiparameter physiological patient monitor, capable of monitoring:

- ECG/Heart Rate
- Invasive blood pressure
- Non-invasive blood pressure
- Respiration
- Pulse oximetry
- Two temperature channels
- Cardiac output
- EtCo2
- Spirometry
- EEG
- BIS Interface (new – subject of this application)

Main components of the VitaLogik:
The VitaLogik system consists of:

(A) a **Bed side computer** with

(B) Display

(A) The Bed side computer acquires, processes, and converts vital signs from the patient into waveforms and digital signals.

The VitaLogik can acquire the following physiological signals of the patient:

- ECG – Waveform and measures Heart Rate, ST and Arrhythmia
- Blood Pressures – Waveform and measures Systole, Diastole and Mean Pressure
- Temperature – As a numeric value in C° or F°
- SpO2 – Photoplethysmographic waveform and numeric value of the oxygen saturation and pulse rate
- NIBP – Systolic, Diastolic and Mean pressure with measuring time stamp
- EtCO2 – EtCO2, inCO2 and Respiration Rate
- BIS – Index of conciseness and EEG waveform

(B) The **Display** is used to display the measurement and waveforms, and alarms. With touch screen option it provides also the control functions, replacing the use of hardware keys. Information from each vital sign is presented in a separate portion of the display. Each vital sign is labeled for identification and numeric value. Displayed Vital sign information can include: Primary Vital Sign Name, waveform, Vital Sign Numeric Value, Alarm Status Message.

Operation of the VitaLogik is accomplished by interaction with front panel controls . A quick-knob control allows direct interaction with displayed menus for direct parameter selection and setup. Where manual entry of alphanumeric information is required, a menu keyboard menu is displayed.

The VitaLogik is a reusable, software driven, patient monitor, intended for use as part of a physiological monitoring system in a hospital environment. As such it is not a life supporting, nor life sustaining device; nor is it implantable and therefore sterility is not a consideration.

The VitaLogik monitors the patient's vital signs. The vital sign data derived by the VitaLogik are presented on the monitor as waveform and numeric displays. The VitaLogik acquire vital signs data from the patient, and display their waveforms and alarms indications on the VitaLogik display.

The VitaLogik is not a kit and does not contain any drug or biological products. The **BIS** Interface of the VitaLogik patient monitor is not sold as a stand alone device, but as part of a multiparameter physiological patient monitoring system (VitaLogik).

In chapter 1, page 1-2 of the VitaLogik Operating Manual, the following Prescription Notice appears: "Federal United States law restricts the sale and use of this instrument to qualified medical personnel only"

Functional description of the new VitaLogik BIS Interface:

(Interface to Aspect BISx device cleared in K 040183)

The BIS Interface is used to monitor dual channel EEG waveform and the BIS index, used to estimate the level of conciseness of patient under anesthesia, or patients in the ICU that may be with limited conciseness.

The BIS index together with several quality parameters are displayed and stored by the VitaLogik monitor.

The parameters displayed and stored by the VitaLogik monitor are the following:

Parameter	Range	Description
BIS	0 – 99	**Bispectral Index:** The measure of consciousness of a patient, (0 = no brain activity), (100 = fully conscious).
EMG	30 – 55 dB	**Electromyography:** The absolute power of muscle activity and artifacts in the 70 - 110 Hz range. Value is in dB with respect to 0.0001 μV_2.
SQI	0 – 100 %	**Signal Quality Index:** The percentage of good epochs and suppressed epochs in the last 120 epochs collected that could be used in the Bispectral Index calculation.
SR	0 – 100 %	**Suppression Ratio:** The percentage of epochs in the past 63 seconds in which the EEG signal is considered suppressed
BC	0 – 30	**Burst Count:** The number of EEG bursts in the last minute. An EEG burst is a momentary period of EEG activity among isoelectric or flat EEG. Blanked if SR is less than 5. Activated by connection of an Extend sensor.
SEF	0.5 – 30 Hz	**Spectral Edge Frequency:** The frequency at which 95% of the total power lies below it and 5% lies above it.

To get these parameters we use Aspect sensor and BISx unit attached to the VitaLogik with an interface cable produced by Aspect.

The BISx is a product of Aspect and is sold to Mennen Medical under OEM agreement.

The BIS sensors, that consist of a set of 4 electrodes, attached to the patients forehead, are Aspect products and will be sold to end users by Aspect directly and not by Mennen Medical.

The function of the VitaLogik BIS Interface and VitaLogik display and storage capabilities is to display the BIS parameter and the quality parameters. To provide alarm limits for the BIS index and provide visual and audible alarms in case of the BIS index being out of the preset range, or in cases that the quality parameters are in such range that they limit the reliability of the BIS index.

The decision on artifacts and limited rellability are provided to the VitaLogik by the BISx Interface. Those can not be set by Mennen Medical VitaLogik monitor. The clinical BIS alarm limits are set by the user, on the VitaLogik monitor.

The Description of the BIS measurement system is described below:

1. The BIS sensor (Made and sold by Aspect) is attached to the patients forehead. (See attached Aspect document: "The BIS™ Family of Sensors")
2. BISx (Figure 1 - OEM by Aspect) is receiving, amplifying and digitizing the EEG brain signals. It analyses the EEG and creates the BIS index and the quality parameters and sends them to the BIS module by RS232 protocol
3. VitaLogik BIS interface receives the BISx output and transfers it to the VitaLogik bedside computer for display and storage.
4. BIS Display and storage: BIS is displayed as a number. EMG and SQI are displayed as vertical bars, and SR and BC as numbers in the BIS display area.
5. Clinical and technical alarm messages are displayed in the BIS display area.

6. Continuous graphic trend of the BIS index and quality parameters are also available on the screen under the label CRG.
7. The real time EEG signal is continuously displayed on the monitor screen.
8. In edition, the VitaLogik provides long term storage and display of the BIS index and its related parameters as numeric Charts and graphic Trends.

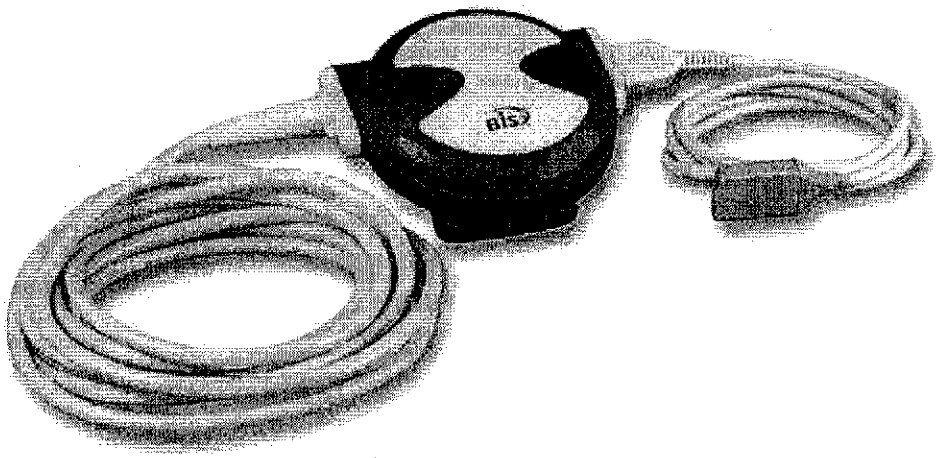


Figure 1: BISx™ device

Substantial Equivalence Discussion

Comparison between the BIS Interface to the VitaLogik with the predicated device- BIS Module to the Envoy

Specification Comparison

	Envoy BIS Module	**VitaLogik BIS Interface**
Part Number	551-147-000	VL 5X00- 640-000-000/640-OPT-080/2 VL 4X00- 681-000-000/681-OPT-080/2
510K	K071899	Subject of this application
Features		
Monitoring profile	BIS numeric + Two EEG + EMG vertical bar + EMG vertical bar + SR, BC numeric + Trend of BIS and EMG	Same
Waveform + Trend	EEG waveform and BIS + EMG graphic trend	Same
Wave scale	5, 10, 25, 50, 100 μV/cm	Same

EEG sweep speed	6.25, 12.5, 25 mm/sec	Same	
BIS Task window	BIS, EEG waveform, EMG, SQI, SR, BC, Alarm limits, Alarm messages	Same	
Data Storage		VL 5x00	VL 4x00
	EEG waveform – 45 days	Same	6 days
	3 month of: BIS, Spectral Edge Frequency (SEF), Electromyography strength (EMG) Signal Quality Index (SQI) Suppression Ratio (SR) Burst Count (BC)	Same	10 days
Electrode Impedance testing	Auto on connection of sensor and Manual any time	Same	
Patient compatibility	Adult and Pediatric	Same	
Input Specification	**Set By BISx**	**Set By BISx**	
Number of channels	Two	Same	
Sweep speed	15, 30, 50 mm/second	Same	
EEG Input signal	+/- 1μV to +/-400 μV	Same	
EEG Bandwidth	0.25 to 100 Hz	Same	
EMG bandwidth	70 to 110 Hz	Same	
DC offset	+/- 300 mV	Same	
Input Impedance	>50 MΩ	Same	
Input Capacitance	<100 pF	Same	
Common Mode rejection	> 110dB	Same	
Input Noise	<0.3 μV RMS (2.0μV peak to peak to peak)	Same	
Smoothing rate	10, 15, or 30 seconds	Same	

Electrical Specification		
Patient leakage currant	< 100 μV	Same
Isolation	4000VAC	Same
Operating Voltage	+5 VDC , +/- 12 VDC	Same
Power consumption	4.5 Watt maximum	Same
Alarms	Audible for High and Low BIS	Same
	Caution alarm	Same
Classification	**MDD** Class IIb **EN 60601-1** Externally powered, rated for continuous operation	Same
Aspect BISx pod	Type BF, defibrillator proof, Body floating applied part	Same
Environmental Requirement		
Storage	Temperature: -15° to 60° C Humidity : 10 to 95% (non-condensing) Altitude: -350 to 5,000m	Same
Operating	Temperature: +5° to 40° C Humidity :10 to 95% (non-condensing) Altitude: -350 to 3,050 m	same

VitaLogik BIS Interface and Envoy BIS module: Similarities and Differences:

Similarities:

The following technological and other characteristic/features apply to both Envoy BIS module and VitaLogik BISx interface:

- Both use Aspect Medical Systems BISx pod as their input device
- Both provide the BISx pod its power (5 Volt)
- Both receive from the BISx by serial data communication the EEG waveform and the BIS parameter together with its quality and related parameters.
- Both have the capability to display EEG waveform and BIS numeric parameters
- Both enable correlation between BIS and other vital signs displayed and stored by the monitor to which the BIS module is inserted.

Differences:

The difference between the VitaLogik BIS interface and the Envoy BIS Module are limited to the method of connection of the BISx to the monitor.

- The Envoy has a BIS module to which the BISx is connected
- The VitaLogik has a universal connector (UIM) to which the BISx is connected

Conclusion of comparison

We consider the VitaLogik BIS interface to be substantially equivalent to the Envoy BIS module

Any differences between to two monitors in the method of BISx connection does not raise any new issues of safety and effectiveness.

The Intended use of the Mennen Medical VitaLogik BIS interface and the predicated device is the same.

Verification, Validation and Testing

The VitaLogik BIS Interface has been subject to extensive performance testing to ensure that the acquisition and display of the patient data and waveforms by the **VitaLogik** with BIS interface are equivalent to the predicate device Envoy with BIS module.

At the system level, SW Validation of the performance of the VitaLogik with BIS interface as compared to the Envoy BIS module, was carried out in accordance with the test plan described in the Mennen Medical Validation Test Procedure for the VitaLogik BIS module.

The SW Test Description for the VitaLogik with BIS interface was derived from the SW Test Description for the VitaLogik, with the necessary addition of the BIS measurements

Final testing for the VitaLogik BIS Interface included performance tests designed to ensure that the device meets all functional requirements and performance specifications, in accordance with the requirements of the Final Test Procedure for the VitaLogik BIS Interface. Electrical Safety testing and EMC testing were performed by an independent testing laboratory (Standard Institute of Israel SII) to ensure that the device complies to applicable industry and safety standards.

The performance of the BIS interface was also tested by Aspect Medical as per the attached certificate (part 21)

Proposed Labeling

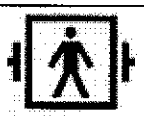
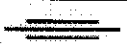
The system will be called **VitaLogik** with BIS Interface

Part numbers

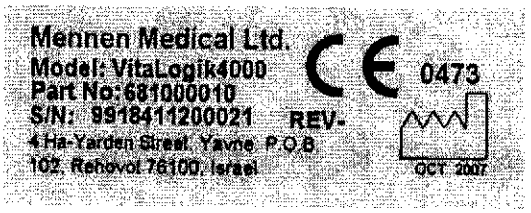
Monitor	Monitor p/n	BIS kit p/n
VitaLogik 5x00	640-000-000	640-OPT 080/2
VitaLogik 4x00	681-000-000	681-OPT 080/2

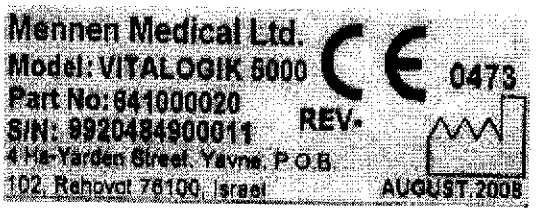
Page 1-2 of the introduction to the VitaLogik User Guide contains the following **Prescription Notice:** "Federal United States law restricts the sale and use of this instrument to qualified medical personnel only."

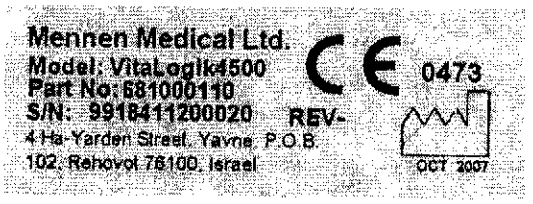
The following symbols appear on page 2-4 of the VitaLogik User's Guides under the section entitled "Label Symbols".

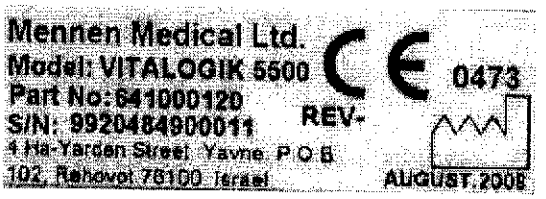
Symbol	Description	Location of Symbol
	Alternating Current	Alternating Current rear of the Processing unit, Isolation Transformer.
	Equipotential	On the rear of the Processing unit
	Attention, consult accompanying documents (Service to be performed by qualified technician, consult service manual before removing cover)	On Isolation Transformer and Processing unit.
	Off (power disconnection from main power supply)	On right of Processing unit
	On (power connection to the main power supply)	On the right of the Processing unit.
	Type BF applied part defibrillator-proof	On NIBP and Sp02
	Type CF applied part - direct cardiac application defibrillator-proof	On ECG, and Dual BP and CO/2 TMP
	Fuse	On rear of Processing unit and Isolation Transformer

labels









Voluntary Standards

The VitaLogik complies with (amongst others) the following voluntary standards:

- **IEC 60601-1:** (2005) Medical Electrical Equipment Part:1 General Requirements for Safety
- **IEC 60601-1-1** (2000) Medical Electrical Equipment Part 1-1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems
- **IEC 60601-1-2** (2007): Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- **IEC 60601-1-4** (2000):
  Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
- **IEC 60601-1-6** (2006):
  Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- **IEC 60601-1-8** (2006):
  General requirements for safety-collateral requirements, test & guidance for alarm system in medical electrical equipment & medical electrical systems
- **IEC 60601-2-27** (2005):
  Medical electrical equipment, Part 2,
  Requirements for safety of electrocardiograph monitoring equipment.
- **IEC 60601-2-30** (1999):
  Medical electrical equipment, Part 2 - requirements for safety of automatic cycling indirect blood pressure monitoring equipment
- **IEC 60601-2-34** (2005):
  Medical electrical equipment, Part 2 - Particular requirements for the safety of direct blood pressure monitoring equipment
- **IEC 60601-2-49** (2006):
  Particular Requirements for the safety of multifunction patient monitoring equipment

- AAMI/ANSI ES1: Safe Current Limits for Electromedical Apparatus, and
- AAMI/ANSI EC13: Cardiac Monitors, Heart Rate Meters and Alarms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mennen Medical Ltd.
% Mr. Ifat Oren
QA and Regulatory Affairs
P.O. Box 102
Rehovot, Israel 76100

DEC 1 6 2008

Re: K083063
Trade/Device Name: BIS interface for VitaLogik Patient monitors
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: September 3, 2008
Received: October 14, 2008

Dear Mr. Oren:

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.

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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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083063

Device Name: **BIS interface for VitaLogik Patient monitors**

Indication For Use

We submit that the intended use and the indications for use of the VitaLogik have been affected by the changes only by the addition of the new BIS parameter. Other aspects of the VitaLogik monitor where not changed.

VitaLogik Indications for Use:

VitaLogik series is intended for use as a multiparameter physiological patient monitoring system.
The VitaLogik series can monitor ECG/heart rate, invasive blood pressure channels, temperature channels, pulse oximetry, respiration, non-invasive blood pressure and EtCO2. This effectively allows the VitaLogik series to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.
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- Critical Care Patients
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- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

BIS - Indication for use

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is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS Index, a processed parameter may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

- The Bispectral Index is a complex technology, intended for use only as an adjunct to clinical judgment and training.
- In addition, the clinical utility, risk/benefit, and application of this device have not undergone full evaluation in the pediatric population.

*The Intended Use of the VitaLogik monitor as indicated above is same as the Indications For Use.

Prescription Use YES AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K083063