K033807

MAR - 9 2004

Special 510(k): Device Modification
DRAEGER Medical Information Bus (MIB/MIBII and MIB Duo) Protocol Converters

---

510(k) SUMMARY
as required per 807.92(c)

Submitters Name, Address:

Draeger Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: Connie Hertel, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: December 5, 2003

Trade Name, Common Name and Classification Name:

A. Trade Name:

Draeger Medical Information Bus (MIB, MIB II, MIB Duo) Protocol Converters

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Transducer Signal amplifier and conditioner	73 DRQ	II	21 CFR 870.2060

Legally Marketed Device Identification:

INFINITY MIB/MIB II / MIB DUO (K022766)
INFINITY MIB II Duo: 510(k) K012461
INFINITY MIB II Protocol Converter: 510(k) K010640
Medical Information Bus (MIB) Protocol Converter:
510(k) K970368, K973222, K991661, K003248, K020277
MVWS and INFINITY Network with INFINITY VentViewer (K003246)

Description of Modification:

Draeger's Infinity Medical Information Bus (MIB/MIBII and MIB Duo) Protocol Converters have received numerous 510(k) clearances for connectivity to third party devices. The release of MIB/MIBII VF4 software enables MIB connectivity of the following Draeger devices to the INFINITY modular monitors:

Narkomed 6000 & 6400
Fabius GS
Savina
Evita XL

These connections enable the display of device specific data on an INFINITY modular monitor. Data from the devices can also be displayed on the VentCentral application (K003246) of the MultiView WorkStation and alarms received from the Evita XL and Savina ventilators annunciated.

The modifications described have not altered the fundamental technology of the MIB/MIBII Protocol Converters.

The intended use and indications of the MIB/MIBII with VF4 software, as described in its labeling, are the same as the intended uses and indications for the MIB/MIBII unmodified predicate devices.

Intended Use:
The Draeger Medical Information Bus (MIB / MIB II) Protocol Converters are intended for use in an environment where patient care is provided by healthcare professionals (Physician, Nurse, Technician) when the professional determines that a third party medical device should be connected to an INFINITY Modular Monitor for display of data.

Connectable devices include: Maquet SV 9000, SV 300, Servo*i* Ventilators, Baxter Vigilance blood gas/continuous cardiac output monitor, Draeger Evita II, IV, EvitaXL, Babylog, & Savina ventilators, Puritan Bennett 7200 & 840 ventilators, Hamilton Galileo ventilator, Draeger Narkomed 6000 & 6400 / Narkomed II & IV Anesthesia Systems, Draeger Julian Anesthesia machine, Ohmeda 7900 Anesthesia Machine, Abbott Oximetrix 3 Blood Gas Analyzer, AVL Medical Instruments: Opti Critical Care Analyzer Portable Blood Gas Analyzer, Optical Sensors Inc.: OSI – Optical CAM, VIA Medical: VIA V-ABG1 Blood Gas Chemistry Monitor; and Aspect A-2000 BIS, Abbott Q2, and Sensormedics Micro Gas 7650.

Assessment of non-clinical performance data for equivalence: Section J

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: 1073.3.1 Medical Device Communications-
Transport Profile-Connection Mode
1073.3.2 – 2000 IEEE Standard for Medical Communications
Transport Profile – IrDA Based – Cable Connected

Draeger Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2004

Ms. Penelope H. Greco
Regulatory Submission Manager
Draeger Medical Systems, Incorporated
16 Electronics Avenue
Danvers, MA 01923

Re: K033807
Trade/Device Name: INFINITY Medical Information Bus Protocol Converter
Regulation Number: 870.2060
Regulation Name: Amplifier and Signal Conditioner, Transducer Signal
Regulatory Class: II
Product Code: DRQ, BSZ, CBK
Dated: February 19, 2004
Received: February 20, 2004

Dear Ms. Greco:

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.

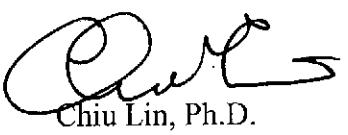
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Infinity Medical Information Bus (MIB) Protocol Converters

Indications for Use:

The Infinity Medical Information Bus (MIB) Protocol Converters (MIB, II & MIB Duo) are indicated for use in an environment where patient care is provided by healthcare professionals (Physician, Nurse, Technician) when the professional determines that third party medical devices that provide data should be connected to a Draeger INFINITY Modular Monitor for display. Such devices include:

Maquet SV 300 ventilator
Maquet Servo*i* Ventilator
Maquet SV900 ventilator
Draeger Evita 2 ventilator
Draeger Evita 4 ventilator
Draeger EvitaXL ventilator
Draeger Savina ventilator
Draeger Babylog ventilator
Draeger FabiusGS Anesthesia System
Draeger Narkomed 2 Anesthesia System
Draeger Narkomed 4 Anesthesia System
Draeger Narkomed 6000 / 6400 Anesthesia Systems
Draeger Julian Anesthesia Machine
Puritan Bennett 7200 ventilator
Puritan Bennett 840 ventilator
Hamilton Galileo ventilator
Ohmeda 7900 Anesthesia Machine
Abbott Oximetrix 3 Blood Gas Analyzer
Abbott Q2 CCO monitor
AVL Medical Instruments: Opti Critical Care Analyzer, Portable Blood Gas Analyzer
Baxter Vigilance blood gas/continuous cardiac output monitor
Optical Sensors Inc.: OSI – Optical CAM
VIA Medical: VIA V-ABG1 Blood Gas Chemistry Monitor
Aspect A-2000 BIS Monitor*
Sensormedics Micro Gas 7650

Note: *The SC 9000 does not support communication with the Aspect BIS Monitor

MRI Compatibility Statement:
The MIB, MIB II and MIB DUO Protocol Converters are not compatible for use in a MRI magnetic field.

Prescription Use ✔ (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)

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

510(k) Number: K033807