K040188

APR 1 4 2004

510(k) SUMMARY

as required per 807.92(c)

Submitters Name, Address:

Draeger Medical Systems, Inc.
16 Electronics Avenue
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Official Correspondent: Connie Hertel, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Regulatory Submissions Manager
Date submission was prepared: January 23, 2004

Trade Name, Common Name and Classification Name:

Trade Name: INFINITY GammaXL and SC 6802XL with Scio

Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
Monitor, Physiological, Patient (with Arrhythmia Detection or Alarms)	MHX	II	870.1025
Arrhythmia Detector & Alarm	74DSI	II	870.1025
System, Network and Communication, Physiological Monitors	MSX	II	870.2300

Legally Marketed Device:

INFINITY GammaXL / SC 6802XL	K033600 / K030313 / K993974
INFINITY Modular Monitors with Scio	K031340

Description of Device Modifications:

The INFINITY GammaXL and SC 6802XL with software version VF3 and above are capable of displaying gas-monitoring data received from a Scio gas module (K031340). Anesthetic gas monitoring is available when a GammaXL or SC 6802XL is attached via a specific cable to a Scio gas module. This is a password protected locked option. The GammaXL and SC 6802XL with Scio are similar to the Infinity Modular Monitors with Scio (K031340) in that they display gas-monitoring parameters received from the Scio gas module. Testing of the INFINITY GammaXL and SC 6802XL with Scio indicate no new issues of safety and efficacy.

Intended Use:

The intended use of this device is to monitor heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, arterial oxygen saturation and pulse rate, central apnea is accomplished through impedance plethysmography and apnea through capnography, end-tidal carbon dioxide, and ST Segment Analysis. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to R50 recorders, either directly or via the INFINITY network.

Assessment of non-clinical performance data for equivalence: Verification and validation testing of the Infinity GammaXL and SC 6802XL with SCIO, indicates no new issues relative to safety and efficacy.

Assessment of clinical performance data for equivalence: The review of clinical data indicates that the GammaXL/SC 6802XL with Scio operates as intended with no adverse affects.

Biocompatability: Not applicable

Sterilization: Not applicable

Standards: Draft Reviewer Guidance for Premarket Notification 510(k) Submissions, November 1993
IEC 601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2004

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

Re: K040188
Trade/Device Name: Infinity Gammaxl and SC 6802XL with the Scio Gas Module
Regulation Number: 868.1500
Regulation Name: Enflurane gas analyzer
Regulatory Class: II
Product Code: NHP, MHX
Dated: April 8, 2004
Received: April 9, 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

510(k) Number (if known): K040188

Device Name: INFINITY GammaXL / SC 6802XL with Scio

Indications for Use:

This device is capable of monitoring:

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

510(k) Number: K040188

- Heart Rate
- Respiration Rate
- Invasive Pressure
- Non-Invasive Pressure
- Arrhythmia
- Temperature
- Arterial oxygen saturation
- Pulse rate
- central apnea accomplished through impedance plethysmography
- apnea accomplished through capnograpy
- end-tidal CO2
- ST Segment Analysis

This Infinity GammaXL and SC 6802XL will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to R50 recorders, either directly or via the INFINITY network.

When connected to a SCIO module sampled breathing gases from adults and pediatrics can be displayed. The gas module continuously measures the content of CO2, N2O, O2 and one of the anesthetic agents, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane in any mixture and communicates real time and derived gas information to the INFINITY monitors.

The device is intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The devices are intended for use in the Adult, Pediatric and Neonatal populations, *with the exception of Arrhythmia and ST Segment Analysis which are not intended for the neonatal population.*

MRI Compatibility Statement:
The INFINITY GammaXL and SC 6802XL are not compatible for use in a MRI magnetic field.

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)