JUN 3 0 2004

K040862

Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness

29 June 2004

Official Contact:	John O'Dea, Ph.D. - General Manager
Proprietary or Trade Name:	Guardian Neonatal CPAP / Humidification Systems
Common/Usual Name:	CPAP system
Classification Name:	Ventilator, non-continuous (Respirator)
Predicate Devices:	EME - Infant Flow systems – K011516 Vapotherm – 2000I – K000401

Device Description

The Guardian Neonate CPAP / Humidification systems is non-invasive respiratory support device for neonatal patients

Intended Use and Environments

Intended Use --	Intended to provide CPAP for use in hospitals to treat newborns and infants less than 5kg body weight with RDS or which are recovering from RDS (Respiratory Distress Syndrome). May or may not include humidification capabilities.
Environment of Use --	Hospital

General Technical Characteristics

Attribute	Guardian CPAP System
Intended to provide CPAP for neonates and infants < 5kg body weight with RDS or recovering from RDS (Respiratory Distress Syndrome)	Yes
Humidification of gases	Yes
Environment of Use – Hospital	Yes
Single patient use circuits and accessories including patient interfaces	Yes
Design Features and Specifications	
CPAP – Range of pressure	2 to 10 cm H_2O
Air / Oxygen mixture	Yes
% O_2 range	21 – 100%
Range of Flow delivered	1 to 15 Lpm (Flow Mode) 1 to 20 L/min (CPAP Mode)
Humidification method	Vapotherm microporous membrane
Range of temperature of gas delivered	33 to 41 °C
Measured Data	
Circuit Pressure (bar graph display) Range	0-12 cm H_2O
% O_2 (window display) - Range	21-100%
Gas temperature - Range	10-50 °C
Flow (bar graph)	Indicator
Power	AC and Battery
Pressure Relief Valve	18 cmH_2O
Alarms	High and Low Pressure High and Low FIO_2 High and Low Temperature
Supply Gases Failure	Air and Oxygen

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed device when compared to the predicate device is safe and effective and is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2004

Mr. John O'Dea
General Manager
Caradyne, Limited
Parkmore Business Centre
Parkmore West
Galway,
IRELAND

Re: K040862
Trade/Device Name: Guardian Neonate CPAP / Humidification System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: June 11, 2004
Received: June 14, 2004

Dear Mr. O'Dea:

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: K040862

Device Name: Guardian Neonate CPAP / Humidification system

Indications for Use:

Intended to provide CPAP for use in hospitals to treat newborns and infants less than 5kg body weight with RDS or which are recovering from RDS. (Respiratory Distress Syndrome) May or may not include humidification capabilities

Prescription Use XX **or** **Over-the-counter use __**
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K040862