K030973

JUL 2 8 2003

8.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

David Osborn
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Cardiac & Monitoring Systems
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This summary was prepared on July 15, 2003.

2. The name of the device is the picoSAT II SpO2 pulse oximetry module. Classification names are as follows:

Device Panel	Classification	ProCode	Description
Anesthesiology and Respiratory Therapy (12624)	§870.2700, II	DQA	Oximeter

3. The new device is substantially equivalent to previously cleared Philips devices M3000A & M3001A marketed pursuant to K971910, K990972, K000822, K013199, and K021300.

4. The modification creates the picoSAT II SpO2 pulse oximetry module for use in host patient monitors.

5. picoSAT II SpO2 pulse oximetry module specifications.

Item	**Specification**
SpO_2 Algorithm	Philips FAST SpO_2 algorithm motion and low perfusion tolerant
SpO_2 displayed range	0% to 100%
SpO_2 accuracy (functional) over the range of 70% to 100% for neonates through adults (reusable probes)	M1191A and M1192A: ± 2.5% M1193A and M1195A: ± 3.0% M1194A: ± 3.0% (adult only)
SpO_2 accuracy (functional) over the range of 70% to 100% for adults and neonates (disposable probes)	M190xA and Nellcor®: ±3.0%
SpO_2 parameter resolution	1%
Pulse Rate parameter range & resolution	30 bpm to 300 bpm ±2% or 1 bpm whichever is greater
FAST SpO_2 parameter averaging	5 s to 20 s
SpO_2 parameter data update period	1 s
Pleth wave height requirement	32 pixels, minimum
Input power	1.8 V to 11.5 V_{dc}, 300 mW max
Serial data interface	3/5 V logic levels, switchable asynchronous data format, 9600 baud 8-bit word with stop, start & parity bit

Item	Specification
Perfusion Indicator	An indicator of SpO_2 signal quality >0.3 indicates that >95% of the time signals are good enough for valid measurements. At 0, no measurement is made.
NBP cuff inflation detection suppression of SpO_2 INOPs & parameter output	SpO_2 and pulse rate parameter output and the SpO_2 Non-pulsatile and Pleth Non-pulsatile INOPs are suppressed for adjustable period of 30 s to 60 s when picoSAT II SpO2 pulse oximetry module detects that an NBP measurement is in progress. SpO_2 EXTD. UPDATE INOP generated after 30 s of suppression.
Technical alarm conditions (INOPs)	Generates the following technical alarm conditions: SpO_2 EQUIP MALF SpO_2 TEST SIGNAL SpO_2 SENSOR MALF NO SpO_2 SENSOR SpO_2 INTERFERENCE SpO_2 LEARNING SpO_2 NOISY SIGN. SpO_2 NON-PULSAT. SpO_2 ERRATIC SpO_2 EXTD. UPDATE SpO_2 LOW PERF

86

6. The new devices have the same intended use as the legally marketed predicate devices. When used in the hospital or patient transport environments, they are intended for the monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates.

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7. The new devices have the same technological characteristics as the legally marketed predicate devices.

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8. Verification testing activities were conducted to establish the performance and reliability characteristics of the new device. Testing involved functional level tests and safety testing from the risk analysis. Clinical validation studies were also conducted.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2003

Mr. David Osborn
Quality Program Manager
Philips Medical Systems
3000 Minuteman Road
Andover, Massachusetts 01810-1099

Re: K030973
Trade/Device Name: PICOSAT II SPO2 Pulse Oximetry Module
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DPZ
Dated: July 15, 2003
Received: July 16, 2003

Dear Mr. Osborn:

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,

for Susan Runner, DDS, MA
Interim 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): K030973

Device Name: picoSAT II SpO_2 pulse oximetry module

Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring, recording and alarming of multiple physiological parameters of adults, pediatrics and neonates in patient transport and hospital environments.

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

510(k) Number: K030973

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)