K083413

DEC 18 2008

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 CFR §807.92.

The submitter of this premarket notification is:

Teresa Schmidt
Regulatory Affairs Specialist
Patient Monitoring
Philips Medical Systems
3000 Minuteman Road, MS0480
Andover, MA 01810-1099

Tel: 978 659 2220
Fax: 978 685 5624
Email: teresa.schmidt@philips.com

This summary was prepared on 17 November 2008.

The name of this device is the **CompuRecord® Peri-Operative Anesthesia Information System Software** Release F.0

Classification names are as follows:

Classification	ProCode	Description
868.5160, II	73 BSZ	Gas Machine, Anesthesia

1. The new device is substantially equivalent to the previously cleared Philips CompuRecord Software, Release D.0 marketed pursuant to K030939.

2. The modifications made to CompuRecord include the following enhancements plus non-safety related bug fixes:

Improved PAE Search
Configurable Paired Events
Improved Case Browser Search
Document Export from Case Browser
Enhanced Vitals Warning
Advanced Reporting Service
Dynamic Anesthesia Worklist
Surgical Outcome Score

5. The new device has the same Indications for Use and Intended Use as the legally marketed predicate devices.

6. The new device has the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that Philips CompuRecord, Release F.0 meets all defined reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2008

Ms. Teresa Schmidt
Regulatory Affairs Specialist
Philips Medical Systems
3000 Minuteman Road, MS 0480
Andover, Massachusetts 01810-1099

Re: K083413
Trade/Device Name: Philips CompuRecord® Peri-Operative Anesthesia Information System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: November 17, 2008
Received: November 18, 2008

Dear Ms. Schmidt:

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 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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

K083413
p. 1 of 1

3.1 ODE Indications Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Philips CompuRecord® Peri-Operative Anesthesia Information System

Indications for Use:

The Philips CompuRecord Peri-Operative Anesthesia Information System Software is a computer-based system which collects, processes, and records data directly from medical monitors which themselves are attached to the patients in the operating room environment.

CompuRecord is generally indicated in the peri-operative environment when the anesthetist decides to generate a paper and electronic version of the administration of anesthesia to a patient, perform a pre-operative assessment, and document (chart) nursing care in the PACU.

Prescription Use ___Yes___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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