K030939

8.0 510(k) Summary

JUL 15 2003

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:

Judith K. Phillips
Philips Medical Systems
Cardiac & Monitoring Systems
1082 Bower Hill Road
Pittsburgh, PA 15243
Tel. 412-279-3263
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This summary was prepared on March 21, 2003

2. The name of this device is the Philips CompuRecord® Peri-Operative Anesthesia Information System. Classification names are as follows:

Regulation No.	Classification Name
None	Computers and software, medical
868.5160	Gas-Machine, Anesthesia
868.1890	Calculator, Drug Dose

3. The new device is substantially equivalent to the previously cleared Philips device marketed pursuant to K854213.

4. The modification is primarily a software based change that updates the operating system and allows network use and web access.

5. The new device has the same intended use as the legally marketed predicate devices. When used in the hospital environment The Philips CompuRecord is intended as a computer-based system which collects, processes, and records data directly from anesthesiological monitors which themselves are attached to patients in the operating room environment. It is indicated in the peri-operative environment when the anesthetist decides to generate a paper and electronic record of the administration of anesthesia to a patient, perform a pre-operative assessment, and documentation [chart] nursing care in the PACU.

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

7. Verification testing activities were conducted to establish the performance and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, integration tests, and safety testing from risk analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2003

Ms. Judith Phillips
Philips Medical Systems
Cardiac & Monitoring Systems
1082 Bower Hill Road
Pittsburgh, PA 15243

Re: K030939
Trade/Device Name: Philips CompuRecord Peri-operative Information System Software
Regulation Number: 21 CFR 868.5160
Regulation Name: Accessory to gas machine for anesthesia or analgesia
Regulatory Class: II
Product Code: BSZ
Dated: June 19, 2003
Received: June 20, 2003

Dear Ms. Phillips:

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,

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): K030939

Device Name: Philips CompuRecord® software

Indications for Use: The Philips CompuRecord® Peri-Operative Anesthesiology Information System Software is a computer-based system which collects, processes, and records data directly from anesthesiological monitors which themselves are attached to 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 record of the administration of anesthesia to a patient, perform a pre-operative assessment, and documentation of [chart] nursing care in the PACU.

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

510(k) Number: K030939

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use**

(Per 21 CFR 801.109)

(Optional Format 1-2-96)