MAY - 9 2003

16. 510(k) Summary K030417

Date Summary Prepared

January 31, 2003

Submitter's Name and Address

Philips Medical Systems
Cardiac and Monitoring Systems
3000 Minuteman Road
Andover, MA 01810-1099

Contact Person

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Device Name

Proprietary Name:	Disposable Sterile Internal Defibrillation Paddles
Common Name:	Internal Defibrillation Paddles
Classification Names:	Low-Energy Internal Defibrillator Paddles

Predicate Devices

The legally marketed devices to which Philips Medical Systems claims equivalence for the Disposable Sterile Internal Defibrillation Paddles are as follows:

- CodeMaster XL+ Defibrillator/Monitor, Philips Medical Systems (formally HP) with the following internal paddle model numbers:

    1. M1742A
    2. M1743A
    3. M1744A
    4. M1785A
    5. M1786A
    6. M1787A

The design of the proposed Disposable Sterile Internal Defibrillation Paddles is substantially equivalent in safety and performance to the device listed above.

Device Description

The Disposable Sterile Internal Defibrillation Paddles are used primarily by physicians in the operating room during intra-thoracic surgical procedures. These paddles are available in both switched and switch-less versions where both versions are available in three different sizes. The paddles are packaged sterile and are single-use only. These paddles will be used in the manner and application as is currently available.

Intended Use

The Philips Disposable Sterile Internal Defibrillation Paddles are for use in manual defibrillation during an intra-thoracic procedure. The device is sterile and single-use only. It must be used by or on the order of a physician.

Comparison of Technology Characteristics

The Philips Disposable Sterile Internal Defibrillation Paddles are used for internal defibrillation in the same manner as the internal paddles currently used with the CodeMaster Defibrillator/Monitors.

Nonclinical Tests Used in Determination of Substantial Equivalence

The testing performed to show substantial equivalence to the CodeMaster internal defibrillation paddles included:

- Bench testing, demonstrating the performance of the Philips Disposable Sterile Internal Defibrillation Paddles to the current re-useable internal paddles.

Conclusion from Testing

Based on the results of the testing described above, it is concluded that the Philips Disposable Sterile Internal Defibrillation Paddles perform in the same manner as the current internal defibrillation paddles. The Philips Disposable Sterile Internal Defibrillation Paddles application does not raise any different questions regarding the safety or effectiveness as compared with the predicate devices. It is considered to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2003

Mr. Peter Ohanian
Director, Quality and Regulatory Affairs
Philips Medical Systems
3000 Minuteman Road, M/S 0222
Andover, MA 01810-1099

Re: K030417
Trade/Device Name: Disposable Sterile Internal Defibrillation Paddles
Regulation Number: 21 CFR 870.5300
Regulation Name: DC-defibrillator (including paddles).
Regulatory Class: II
Product Code: LDD
Dated: February 3, 2003
Received: February 10, 2003

Dear Mr. Ohanian:

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use

510(k) Number (if known): K030417

Device Name: Disposable Sterile Internal Defibrillation Paddles

Indications For Use: The Philips Disposable Sterile Internal Defibrillation Paddles are for use in manual defibrillation during an intra-thoracic procedure. The device is sterile and single-use only. It must be used by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030417