DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2004

Zoll Medical Corporation
c/o Mr. Sean Reynolds
Regulatory Affairs Engineer
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824-4105

Re: K042302
Trade Name: Zoll Autoclavable Internal Handles, Zoll Autoclavable Internal Handles with Integrated Electrodes and Zoll Autoclavable External Paddles
Regulation Number: 21 CFR 870.5300
Regulation Name: DC–Defibrillator (including paddles)
Regulatory Class: II (two)
Product Code: LDD
Dated: August 24, 2004
Received: August 25, 2004

Dear Mr. Reynolds:

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation.
Center for Devices and
Radiological Health.

Enclosure

Indications for Use

510(k) Number (if known): K042302

Device Name: **ZOLL Autoclavable Internal Handles,**
ZOLL Autoclavable Internal Handles with Integrated Electrodes,
ZOLL Autoclavable External Paddles

Indications For Use:

The ZOLL Autoclavable Internal Handles are to be used with interchangeable electrodes and a manually operated ZOLL Defibrillator to defibrillation therapy directly to the heart during surgical procedures.

When used with a ZOLL Defibrillator equipped with an advisory or ECG analysis feature, the ZOLL Autoclavable Internal Handles allows the defibrillator to operate only as a manual device.

The ZOLL Autoclavable Internal Handles are intended for use by or under the direction of a physician.

The ZOLL Autoclavable Internal Handles with Integrated Electrodes are to be used with a manually operated ZOLL Defibrillator to provide defibrillation therapy directly to the heart during surgical procedures.

When used with a ZOLL Defibrillator equipped with an advisory or ECG analysis feature, the ZOLL Autoclavable Internal Handles with Integrated Electrodes allows the defibrillator to operate only as a manual device.

The ZOLL Autoclavable Internal Handles with Integrated Electrodes are intended for use by or under the direction of a physician.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042302

Indications for Use
(continued from previous page)

The ZOLL Autoclavable External Paddles are to be used with manually operated ZOLL M Series Defibrillator products to perform closed chest defibrillation of a patient when sterilization of the paddles is required either before or after the defibrillation event.

The ZOLL Autoclavable External Paddles are intended for use by trained personnel and are for use on Adult patients only.

The ZOLL Autoclavable External Paddles are intended for use by or under the direction of a physician.

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