DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

ZOLL Medical Corporation
c/o Mr. Scott August
Quality Assurance Engineer
269 Mill Road
Chelmsford, MA 01824

Re: K032439
Trade Name: M Series Bi-Phasic Option
Regulation Number: 21 CFR 870.5300
Regulation Name: Low Energy DC – Defibrillator (including paddles)
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: August 7, 2003
Received: August 7, 2003

Dear Mr. August:

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

510(k) Number (if known): K032439

Device Name: M Series Bi-Phasic Option

Indications for Use:

The ZOLL M Series Bi-Phasic Defibrillator is to be used only by qualified medical personnel for converting ventricular fibrillation (VF), a cardiac rhythm incompatible with life, and/or Ventricular Tachycardias (VT) to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

In addition, this product is to be used in the synchronized cardioversion mode only by qualified medical personnel to terminate Atrial Fibrillation (AF) at lower energy and currents than monophasic defibrillators. A qualified physician must decide when synchronized cardioversion is appropriate.

In addition, this product is to be used in the synchronized cardioversion mode only by qualified medical personnel to terminate Ventricular Tachycardias (VT). A qualified physician must decide when synchronized cardioversion is appropriate.

The Rectilinear Biphasic Waveform (RBW) has been successfully tested in multi-center, prospective, randomized, transthoracic defibrillator VT/VF and AF clinical trials, proven to defibrillate and cardiovert adult patients at lower energies and currents than existing monophasic devices. The M Series Biphasic option incorporates some user selectable energy settings, which are lower than those used during those clinical trials.

There are currently no clinical studies related to the use of the Rectilinear Biphasic Waveform (RBW) in pediatric applications.

The AED or advisory function should only be used to confirm the presence of ventricular fibrillation in patients meeting the following clinical criteria:

- the patient should be unconscious and unresponsive
- the patient should be apneic (not breathing)
- the patient should be pulseless

Warning Do not use the units AED function on patients under the 8 years of age. (Per AHA Guidelines for Adult Cardiopulmonary Resuscitation and AED, 3-5, 1998).

(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 Cardiovascular Devices
510(k) Number K032439