DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 1999

Mr. Paul Dias
QA Engineer
ZOLL Medical Corporation
32 Second Avenue
Burlington, MA 01803-4420

Re: K990762
ZOLL M Series Bi-Phasic Option
Regulatory Class: III (three)
Product Code: 74 MKJ, DRO, LDD, and DPS
Dated: July 2, 1999
Received: July 7, 1999

Dear Mr. Dias:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

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On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please not the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers 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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) NUMBER (IF KNOWN): k990762

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, and 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. or

~~The M Series Biphasic option is not indicated~~ for direct defibrillation of the heart during open chest surgical procedures.

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 unit's AED function on patients under 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 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)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number