

K982992

3/11/99

## Summary of Safety and Effectiveness

### Defibrillators

The types of safety and effectiveness problems associated with advisory defibrillators are summarized below:

The five most frequently reported problems that were MDR-related:

1. Non-clearable message prompts (e.g. "check electrode", "motion detected", etc.)
2. Device shutdown resulting in inability to defibrillate.
3. Inappropriate rhythm analysis resulting in either a false positive or false negative.
4. Inappropriate activation of alarms. ("check patient" falsely indicating patient in shockable rhythm)
5. Failure to analyze rhythm

This list is based on the analysis of all MDRs related to AEDs which was presented by Kimberly Trautman of the FDA Office of Compliance at the FDA Meeting with Manufacturers of Automatic External Defibrillators September 23, 1994.

From the perspective of overall complaints (as opposed to strictly MDRs), ECRI presented the results of a questionnaire regarding total number of complaints. This list is part of the same record as Kimberly Trautman's presentation is found. Copies of ECRI's and Ms. Trautman's discussion contained in the Federal Record are included in this section for convenience. ECRI's list is summarized below:

1. Tape Deck or other data recording device.
2. Service Messages
3. Check electrode or motion detection message
4. Inappropriate rhythm analysis
5. Won't analyze charge, or discharge
6. Won't power up
7. Monitor/display
8. Miscellaneous
9. Battery
10. Device shuts off

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The top 5 MDRs from 1996, in order of frequency, associated with ZOLL Advisory and Semi-automatic Defibrillators are as follows:

1. Non-clearable message prompts
2. ECG signal problems
3. Video display
4. Device shutdown
5. Inappropriate analysis

Also, a literature search of the National Library of Medicine (MEDLINE) was conducted. Copies of the abstracts from this literature search are contained on pages 2-35 to 2-79.

### Pacemakers

The types of safety and effectiveness problems associated with pacemakers are summarized below. This information was obtained from the DIOGENES database.

The five most frequently reported problems that were MDR-related:

1. Failure to pace (i.e. no output, very low output, failure to power up, pacing inhibited)
2. Failure to achieve or maintain electrical capture
3. Pacer current or rate out of specification
4. Miscellaneous
5. Unclear or Undefined malfunction.

The top 5 MDRs from 1996, in order of frequency, associated with ZOLL Pacemakers are as follows:

1. Unable to capture
2. No pacemaker output
3. User received unintended pacemaker pulse (user error)
4. Pacer current or rate out of specification
5. Unable to adjust pacemaker rate.

Also, a literature search of the National Library of Medicine (MEDLINE) was conducted (1996 to present). Copies of the abstracts from this literature search are contained on pages 2-80 to 2-142.

This Class III Summary, in conjunction with the Hazards Analysis included in Section 8 of this 510(k), indicates that ZOLL Medical Corporation is fully cognizant of the types of safety and effectiveness problems associated with this type of device. This knowledge, combined with over ten years of experience in

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designing and manufacturing similar types of devices, has led the company to make every effort to ensure that the proposed design minimizes the potential for similar problems.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 11 1999

Ms. Maura McGuire  
Zoll Medical Corporation  
32 Second Avenue  
Burlington, MA 01803-4420

Re: K982992  
Zoll M-Series Defibrillator SpO2 Option  
Regulatory Class: III (three)  
Product Code: 74 MKJ  
Dated: December 18, 1998  
Received: December 22, 1998

Dear Ms. McGuire:

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 (Pre-market 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.

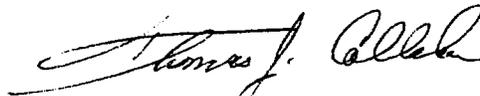
Page 2 - Ms. Maura McGuire

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) 594-4692. 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" (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): K982992

DEVICE NAME: ZOLL M Series Defibrillator SpO2 Option

INDICATIONS FOR USE:

The ZOLL M Series Pulse Oximeter with Masimo SET® technology and the LNOP® Series of Sensors are indicated for the continuous noninvasive monitoring of arterial oxygen saturation (SpO<sub>2</sub>) and pulse rate during both no motion and patient motion conditions for adult patients, and no motion conditions for pediatric and neonatal patients, in a hospital and pre-hospital environment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

Mark Kramer

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

510(k) Number \_\_\_\_\_