JUL 1 1 2003

K030547

510(k) SUMMARY
Guardian Angel Product's ZAP GUARD II

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Guardian Angel Products, Inc.
2771 Philmont Ave
Huntingdon Valley, PA 19006

Phone: 215-938-7677
Facsimile: 215-947-2280

Contact Person: Ernest H. Pescatore
Date Prepared: June 2003

Name of Device and Name/Address of Sponsor/Applicant

ZAP GUARD II

Guardian Angel Products, Inc.
2771 Philmont Ave
Huntingdon Valley, PA 19006

Common or Usual Name: Defibrillator Testing Probe

Classification Name: Tester, Defibrillator

Predicate Devices: ZAP GUARD (K896985)

Purpose of 510(k):

The purpose of this Special 510(k) is to modify the ZAP GUARD device used for testing monophasic defibrillator systems. The differences between the devices is that the resistor configuration of the new device was modified for use in testing biphasic defibrillator systems.

Intended Use:

The ZAP GUARD II is intended to be used for the testing of the continuity and the integrity of the wires of Biphasic Defibrillator Systems.

Technological Characteristics:

The ZAP GUARD II device consists of an electrical circuit incorporating resistors and a neon light within the pathway. Upon contact with the paddles of a biphasic defibrillator system which is operational, energy is delivered through the circuit. If the defibrillator system's wires are intact and energy delivery is continuous, then the neon lamp will illuminate.

Performance Data

Bench testing demonstrated that the ZAP GUARD II conforms to the original voltage and amperage design specifications. The ZAP GUARD II was also functionally tested using a biphasic defibrillator and performed as expected.

Substantial Equivalence

The Zap Guard II has the same intended use, principles of operation, and technological characteristics as the original ZAP GUARD device. The minor differences in the ZAP GUARD II do not raise any new questions of safety or effectiveness. Performance data demonstrates that the ZAP GUARD II is as safe and effective as the original ZAP GUARD. Thus, the ZAP GUARD II is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2003

Guardian Angel Products, Inc.
c/o Mr. Ernest Pescatore
2771 Philmont Avenue
Huntingdon Valley, PA 19006

Re: K030547
Trade/Device Name: Zap Guard II Defibrillator Test Probe
Regulation Number: 21 CFR 870.5325
Regulation Name: Defibrillator tester
Regulatory Class: Class II (two)
Product Code: DRL
Dated: June 11, 2003
Received: June 11, 2003

Dear Mr. Pescatore:

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 Statement

510(k) Number (if known): K030547

Device Name: ZAP GUARD II

Indications for Use:

The ZAP GUARD II is intended to be used for testing the continuity and integrity of the wires of Biphasic Defibrillator Systems.

(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 K030547

Prescription Use X OR Over-The-Counter Use___
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)