



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James D. Quinn
Metron U.S., Inc.
1345 Monroe N.W., Suite 244
Grand Rapids, Michigan 49505

JUL - 1 1997

Re: K963190
QA-40M Difibrillator Tester
Regulatory Class: II (two)
Product Code: 74 DRL
Dated: April 2, 1997
Received: April 4, 1997

Dear Mr. Quinn:

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 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). 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 (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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 sections 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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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 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/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

Enclosure

510(k) Number (if known):

Device Name: Defibrillator Tester

Indications for Use:

The Metron U.S. *QA-40M Defibrillator Analyzer* is a precision instrument for testing defibrillators, and for ensuring that defibrillators comply with the specified requirements.

The *QA-40M* tester is a device that is connected to the output of a defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load and can also provide waveform information. The *QA-40M* test for ANSI/AAMI DF39 standards.

The *QA-40M Defibrillator Analyzer's* main function is to measure the energy output of a defibrillator. The instrument has a built-in load resistance of 50 ohm, which roughly corresponds to the impedance of the human body. The defibrillator pads are placed on the *QA-40M* contact plates. Thus, the defibrillator is connected through load resistance. When the defibrillator is discharged, *QA-40M* will calculate and display the energy delivered.

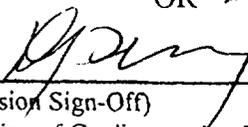
The *QA-40M Defibrillator Analyzer* performs the following tests and features (1) energy and cardioversion measurement, (2) peak voltage and current reading, (3) storage and playback of output waveform, (4) 12 lead ECG simulation. (5) ECG, performance and arrhythmia simulation, (6) transcutaneous cardiac pacemaker testing (module is optional), (7) integrated pacemaker loads selectable from 50 ohm to 2500 ohm, (8) automatic defibrillator test procedures, (9) large graphic display and (10) RS-232C and Centronic printer interface.

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

Prescription Use
 Use _____
 (Per 21 CFR 801.109)

OR - Over-the-Counter,


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

510(k) Number K963190