



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 20 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Byron Zahler  
TZ Medical Inc.  
15858 SW Upper Boones Ferry Road  
Lake Oswego, OR 97035

Re: K993205  
Booker Box Defibrillation Cable Adapter, Model Pad 5001  
Regulatory Class: II (two)  
Product Code: 74 LDD, DSA  
Dated: March 18, 2000  
Received: April 21, 2000

Dear Mr. Zahler:

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, 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.

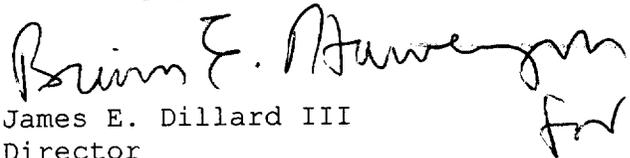
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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, 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 pre-market 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.

Page 2 - Mr. Bryon Zahler

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) 594-4586. 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" (21CFR 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,

A handwritten signature in black ink that reads "James E. Dillard III". The signature is written in a cursive style and is positioned above the typed name and title.

James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known) K993205

Device Name: Booker Box Defibrillation Cable Adapter and Adapter/Connectors

Indications For Use:

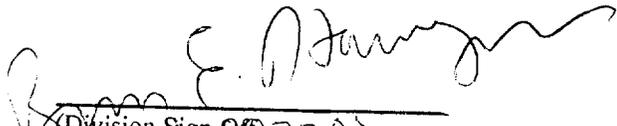
The Booker Box is passive connector, which allows connection to two defibrillators at a time to allow the physician to place a back up pair of electrodes. When the device is connected to two separate low energy defibrillators (using the adaptor/connectors compatible with the individual defibrillator) and disposable electrodes, energy from the defibrillator passes through the device to the external disposable electrodes. Should the physician need to the second set of electrodes are used as a back up in case the first pair configuration is unable to convert. The device also can be connected to a generic physiologic monitor recorder cable to allow unipolar recording using one of the back electrodes.

1. Provides simultaneous connection to two defibrillators, which allows placement of a set of back-up electrodes
2. Provides connection to generic physiologic monitor recorder cable for unipolar recording from using a back electrode.
3. Used in Hospitals/EP Laboratories
4. Used with manual defibrillators and has been tested with the following devices:

Hewlett Packard CodeMaster  
 Hewlett Packard 7600, 7800  
 Zoll PD1200, PD1400, "M" Series  
 Siemans 410  
 PhysioControl LifePak LP5, LP6, LP8, LP9, LP10 and LP 12

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

\_\_\_\_\_  
Concurrence Of CDRH, Office OF Device Evaluation (ODE)

  
 Division Sign-Off K993205  
 Division of Cardiovascular, Respiratory,  
 and Neurological Devices  
 510(k) Number \_\_\_\_\_

Prescription Use   
(Per 21 CFR 801.109)

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)