SEP 14 2005 K050524

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Per 21 CFR 807.92)

General Company Information

Name: Marda Medical, Inc.

Contact: Howard Schrayer
Regulatory Affairs Consultant

Address: 895 NE Dixie Highway
Suite 201
Jensen Beach, FL 34957

Telephone: (772) 225-3111

Date Prepared: August 20, 2005

General Device Information

Device Name: EZ-IV Medical Pad Warming Unit, Model 1000

Common Name: Powered Heating Unit

Classification: Class I – Product Code IRQ
21 CFR 890.5950

Predicate Device: Thermalator. Models T-4-S, T-8-S, etc

Description: The EZ-IV Medical Pad Warming Unit, is a compact, portable, tabletop size medical device, used to warm factory sealed medical prep pads (alcohol and povidone iodine), with a pre-set maximum temperature of 55° C. A lid covers the unit to minimize any heat loss from the medical pads. Inside the unit are four individual compartments, in which the sealed pads are placed. Each compartment has it's own, inner lid. The front of the device has a membrane keypad to control the device function.

Intended Use: (Indications) The EZ-IV Medical Pad Warming Unit is intended to warm alcohol and povidone iodine skin cleansing pads for use in gaining venous access during intravenous fluid and / or medication administration and to facilitate phlebotomy procedures.

SE: The EZ-IV Medical Pad Warming Unit, is a medical device, and Marda Medical, Inc. believes it falls within the same Federal Regulation Number 21 CFR 890.5950, as the predicate device. Marda Medical believes the EZ-IV Medical Pad Warming Unit has the same technological characteristics, and is substantially equivalent to the predicate device. It differs in that the Thermalator warms it's contents with a water bath, while the EZ-IV Medical Pad Warming Unit employs simple radiant heating.

Efficacy: A clinical study was conducted during which alcohol pads were warmed to a temperature of 40° C before being used to facilitate intravenous access in pediatric patients. The results showed a statistically significant reduction in the number of venous access attempts (needle sticks) when warmed alcohol pads were used, compared with the use of non-warmed, room temperature alcohol pads. A second clinical evaluation showed a significant decrease in time required for venous access when warmed alcohol and povidone iodine pads were used compared to room temperature pads. A microbial analysis demonstrated that heated pads are equivalent to room temperature pads in their ability to reduce microbial load on the patient's skin.

Safety: Infrared spectrometer analyses showed the device does not affect the chemical composition of the alcohol and betadine pads when warmed at 58° C for 96 hours and 80° C for 24 hours. Additional studies showed the device does not adversely affect the sterility of the alcohol and povidone iodine pads when warmed at 58° C for 96 hours. Underwriters Laboratories certification shows there are no electrical safety issues.

Conclusions: Marda Medical Inc. believes that the information provided establishes that the EZ-IV Medical Pad Warming Unit performs a similar function to that of other, legally marketed, devices, namely the warming of patient contact materials to provide patient benefit. The devices intended for distribution by Marda Medical have been tested to assure compliance with requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2005

Mr. Howard Schrayer
Marda Medical, Inc.
895 NE Nixie Highway, Suite 201
Jensen Beach, Florida 34957

Re: K050524
Trade/Device Name: EZ-IV Medical Pad Warming Unit, Model 1000
Regulation Number: 21 CFR 890.5950
Regulation Name: Powered heating unit
Regulatory Class: I
Product Code: IRQ
Dated: August 24, 2005
Received: August 25, 2005

Dear Mr. Schrayer:

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.

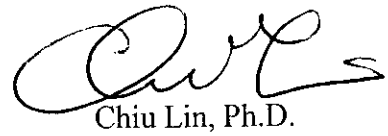
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(k) Number (if known): K050524

Device Name: EZ-IV Medical Pad Warming Unit

Indications For Use:

The EZ-IV Medical Pad Warming Unit is intended to warm alcohol and povidone iodine skin cleansing pads for use in gaining venous access during intravenous fluid and / or medication administration and to facilitate phlebotomy procedures.

Prescription Use____X___ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman for NPW 9/14/05

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050524