K023083

SILBERG'S VEIN PREPARATION SYSTEM
MODEL ME 800
510(K) SUMMARY STATEMENT (KXXXXXX)

FEB 2 8 2003

Submitter's Name: Mettler Electronics Corp.
Address: 1333 South Claudina Street
Anaheim, CA 92805

Telephone: 714-533-2221

Contact: Robert E. Fleming
Director, QA/RA

Date Prepared: September 16, 2002

Proposed Device Name:

a. TRADE NAME:	Silberg T.P.S., Model ME 800
b. CLASSIFICATION NAME:	Ultrasonic Physiotherapy
c. COMMON NAME:	Ultrasonic Physiotherapy

Predicate Devices:

TRADE NAME:	510(k) Number
Sonicator 716, Model ME 716	K934846
Irrigation or Infusion Pump "K" Pump	K991203

Description of Proposed Device:

The Silberg Tissue Preparation System, Model ME 800, consists of a 1 MHz ultrasonic generator, 10 cm^2 ultrasonic applicator, peristaltic pump irrigation unit, foot switch, hollow cannula, system cart, IV pole with saline solution bag and irrigation tubing set.

Proposed Device Intended Use Statement:

510(k) Number: TBD

Device Name: Silberg Tissue Preparation System, Model ME 800

Indication for use:

1. Ultrasonic dispersion of infused subcutaneous fluid prior to saphenous vein harvesting for coronary artery bypass graft surgery.

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Comparison of Technological Characteristics Between Proposed and Predicate Devices:

The ultrasound portion of the Tissue Preparation System is functionally and electrically the same as the Sonicator 716, ME 716, ultrasound therapy device (K934846). The only difference is the housing in which the ME 716 is installed. It is a non-conductive plastic housing containing the ultrasound component and subassemblies along with the pump and controller electronics for the saline delivery system that complements use of ultrasound to prepare tissues for vein removal.

The peristaltic irrigation pump and controller system is the same as the Barnant pump system used by the KMI Kolster Methods, Inc. "Irrigation or Infusion Pump 'K' Pump" (K991203). It is driven by a foot switch with relative flow rate controlled by front panel potentiometer and provides the saline solution for hydration of tissues in preparation for vein removal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2003

Mettler Electronics Corporation
Robert E. Fleming
Director, QA/RA
1333 South Claudina Street
Anaheim, California 92805

Re: K023083
Trade/Device Name: Silberg T.P.S., Model ME 800
Regulation Number: 880.5725; 890.5860
Regulation Name: Infusion pump; Ultrasound and muscle stimulator for use in applying therapeutic deep heat
Regulatory Class: Class II
Product Code: FRN; IMG
Dated: November 26, 2002
Received: December 2, 2002

Dear Mr. Fleming:

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) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Enclosure 1)

K023083

INDICATIONS FOR USE STATEMENT

SILBERG T.P.S. (Tissue Preparation System), ME 800

Indication for use:

The one megahertz ultrasound/peristaltic irrigation pump combination system, trade name Silberg T.P.S. (Tissue Preparation System), provides a method for the subcutaneous infusion and ultrasonic dispersion of tumescent fluid. It is not indicated for the administration of parenteral fluids, infusion of drugs, or for any life-sustaining purpose.

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023083