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March 11, 2003

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Citizen Petition

Certified by:



EN ISO 9001
EN 46001

MDD 93/42/EEC Annex II

The undersigned submits this petition under 519(e) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to revoke an medical device tracking order.

Action requested

A copy of the Medical Device Tracking Order dated March 5, 2003 and sent to Mettler Electronics Corp. at 1333 South Claudina Street, Anaheim, CA 92805 regarding Infusion Pump (K023083) used in model ME 800, Silberg Tissue Preparation System (T.P.S.) is enclosed.

Statement of grounds

Section 519(e) of the Act, as amended, states that FDA, "...may by order require a manufacturer to adopt a method of tracking a class II or class III device---"

- (A) the failure of which would be reasonably likely to have serious adverse health consequences; or
- (B) which is—
 - (i) intended to be implanted in the human body for more than one year, or
 - (ii) a life sustaining or life supporting device used outside a device user facility."

The ME 800, Silberg Tissue Preparation System (T.P.S.) is none of these. This device is intended to be used for subcutaneous infusion and ultrasonic dispersion of tumescent fluid (saline solution) by licensed healthcare professionals in device user facilities only and should never be used outside a device user facility. As the indications for use statement in the 510(k) submission (K023083) states, "It is not indicated for the administration of parenteral fluids, infusion of drugs, or for any life-sustaining purpose."

We believe that this class II device does not pose the degree of risk that lead to the enactment and implementation of medical device tracking under section 519(e) of the Act. The nature of this device and its intended use insure the exercise of reasonable caution and safety expected of licensed healthcare professionals in an operating room environment. There is no conceivable way in which , or plausible reason why, it would be used outside a hospital/clinical environment such as a patient's home.

We know of no information unfavorable to this position.

03P-0105

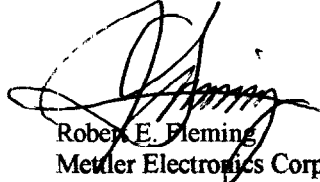
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Per 21CFR10.30, we claim categorical exclusion under Secs. 25.30, 25.31, 25.32, 25.33, or Sec. 25.34 of this chapter.

Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Robert E. Fleming
Mettler Electronics Corp.
1333 South Claudina Street
Anaheim, CA 92805
1-800-854-9305 x314

enclosure

Copy of Medical Device Tracking Order dated March 5, 2003
to Mettler Electronics Corp.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Medical Device Tracking Order

Mr. Robert Fleming
Mettler Electronics Corporation
1333 South Claudina Street
Anaheim, California 92805

MAR - 5 2003

RE: Infusion Pump (K023083)

Dear Mr. Fleming:

You are notified by this letter of your obligation to adopt a method of tracking for the devices referenced above, as authorized by section 519(e) of the Federal Food, Drug, and Cosmetic Act, (the Act) as amended by section 211 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The implementation of section 519(e) of the Act, as amended, requires the Food and Drug Administration (FDA) to issue an order to manufacturers when FDA determines that a person who manufactures and distributes a device meets the relevant statutory requirements and tracking is required to protect the public health. This order is effective immediately.

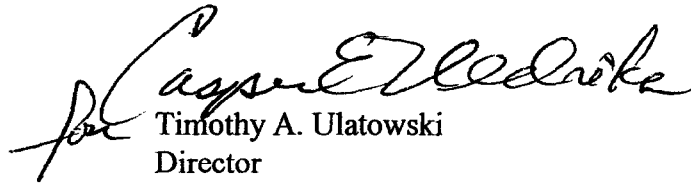
Section 519(e) of the Act, as amended, states that FDA, "...may by order require a manufacturer to adopt a method of tracking a class II or class III device—

- (A) the failure of which would be reasonably likely to have serious adverse health consequences; or
- (B) which is—
 - (i) intended to be implanted in the human body for more than one year, or
 - (ii) a life sustaining or life supporting device used outside a device user facility."

As you know, the corresponding medical device tracking regulations, found in Title 21 Code of Federal Regulations (CFR) Part 821, are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person by whom the device is intended to be used when patient notification (under section 518(a) of the act) or device recall (under section 518(e) of the act) actions are ordered by the agency. The device tracking requirements for exemptions and variances, system and content requirements of tracking, the obligations of persons other than device manufacturers, such as distributors, records and inspection requirements, confidentiality, and record retention requirements, which were published in the **Federal Register** on August 16, 1993, remain in effect. (21 CFR sections 821.2, 821.25, 821.30, 821.50, 821.55 and 821.60, copy enclosed.)

This order to adopt a tracking method does not change your obligations concerning other existing FDA regulations affecting your device. FDA published in the **Federal Register** on February 28, 2002, an amendment to the final rule to revise the scope of the regulation and add certain patient confidentiality requirements, and non-substantive changes to remove outdated references and simplify terminology. (67 FR 6943) Please contact Chet Reynolds in the Office of Compliance at (301) 594-4618 if you need specific guidance. Other general information on your responsibilities under the Act, or more specific information, such as non-binding guidance on medical device tracking, 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 the internet address www.fda.gov/cdrh.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski". The signature is written in a cursive style with a large initial "T" and "U".

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure