

SEP 30 1998

ATTACHMENT 9

K982781
510(k) SUMMARY

(As required by 21 C.F.R. §§ 807.87(h), 807.92)

1. **Manufacturer** Thermal Waste Technologies, Inc.
19 Stony Hill Road
Bethel, CT 06801
(203) 778-2210
2. **Contact Person** Bill Ransone
Vice President Sales & Marketing
(203) 778-1039
3. **Device**
 - a. **Trade or Proprietary Name** Demolizer® #47 One-Gallon Point of Generation Sharps Container
 - b. **Common Name** Sharps Container
 - c. **Classification Name** Accessory to Hypodermic Needle
 - d. **Classification** II
4. **Intended Use:** The sharps container is intended for the collection of disposable sharps in both clinical and nonclinical healthcare settings, such as laboratories, dentists' offices, doctors' offices, veterinarian offices, corporate clinics, nursing homes, and other types of healthcare centers.
5. **Predicate Devices**

The Demolizer # 47 One-Gallon Point of Generation Sharps Container is substantially equivalent to the 1.0 Gallon Leaktight Locking Top Translucent Red Sharps Disposal Container marketed by Post Medical, Inc. (#K925816), and to the 5-Quart Round Sharps Container marketed by Sage Products, Inc. (#K943659).
6. **General Description**

The Demolizer # 47 One-Gallon Point of Generation Sharps Container is a single use, non-sterile, disposable, point of generation sharps container, constructed out of tin-plated steel. The device has a friction fit lid and black foam plastisol sealant for container closure. It is designed to hold contaminated disposable sharps, such as various-sized hypodermic, intravenous syringes or other medical needles, scalpel blades, disposable knives and lancets, and broken glass such as slides, slip covers and ampoules. The device is not a secondary container.

7. **Detailed Description**

The sharps container is a three-piece construction, one-gallon metal drum with a friction fit lid and sealant used to close the container. The minimum nominal body wall thickness is .0094 inches, and the minimum nominal top/bottom thickness is .0097 inches. The container is opaque and measures 6-5/8 inches wide by 7-7/16 inches in height, with a 2-3/8 inch sharps inlet opening in the center of the top of the container. The lid is 2-3/4 inches in diameter, with a thickness of .0088 inches. Lining the perimeter of the posterior side of the lid is a black foam plastisol which acts as an additional safety seal; this foam ensures a closed container. A built-in vent port, approximately 1 mm in diameter, is located on the top of the sharps container.

8. **Summary of Technological Characteristics**

The Demolizer # 47 One-Gallon Point of Generation Sharps Container differs slightly from its predicate devices, in that the Demolizer sharps container is constructed of tin-plated steel and lap welded. The two predicate devices are constructed of plastic. Further, unlike the predicate devices, once the Demolizer sharps container is closed, it is resistant to manual opening.

The Demolizer sharps container is similar to the two predicate devices, in that all are single use, disposable, nonsterile, opaque containers of roughly the same capacity, and all feature vertical inlet openings for the disposal of sharps.



MAR 27 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bill Ransone
Vice President Sales & Marketing
Thermal Waste Technologies, Incorporated
19 Stony Hill Road
Bethel, Connecticut 06801

Re: K982781

Trade/Device Name: Demolizer #47 One-Gallon Point of Generation Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Codes: MMK
Dated: August 26, 1998
Received: August 31, 1998

Dear Mr. Ransone:

This letter corrects our substantially equivalent letter of September 30, 1998.

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 (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.

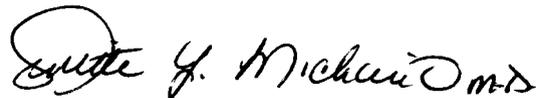
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 <http://www.fda.gov/cdrh/organiz.html#OC> for OC organization structure). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu S. Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 11

INDICATIONS FOR USE STATEMENT

(REVISION)

Page 1 of 1

510(k) Number: K982781

Device Name: Demolizer #47 One-Gallon Point of Generation Sharps Container

Indications for Use: This device is intended for the disposal of various-sized contaminated medical sharps (including needles, syringes, slides, and ampoules) in clinical and laboratory healthcare settings.

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)
Division of ~~Medical~~ Infection Control,
and General Hospital Devices

510(k) Number K982781

Prescription Use
(Per 21 C.F.R. § 801.109)

OR

Over the Counter Use