

510(k) SUMMARY

1970383 JUL 3 1997

THIS SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION IS BEING SUBMITTED IN ACCORDANCE WITH THE REQUIREMENTS OF SMDA 1990.

510(k) Summary of Safety & Efficacy: Horizontal Entry Sharps Container

Submitted By: Custom Medical Plastics, Inc. 11811 Calhoun Road
Omaha, NE 68122 (402) 691-2855
Contact: Daniel R. Brown, President
Date Prepared: December 24, 1996 (Ammended April 4, 1997)

Our Horizontal Entry Sharps Container consists of an injection-molded polypropylene container fitted with a snap-on, leak-resistant, poly-propylene lid. The lid has a "mail-box" style raised opening into which the sharps are dropped horizontally. When the container is full, a unique butterfly closure system closes to prevent over-filling and to prevent access to the sharps inside.

Sharps Containers are classified as a Class II accessory to a hypodermic needle (21 CFR Section 880.5570); Panel 80 FMI.

Our Horizontal Entry Sharps Container is substantially equivalent to Horizontal Entry Sharps Containers manufactured by Sage Products Inc. and Sherwood Medical. These containers are all made of polypropylene by the injection molding process. They feature a mechanism for inserting the sharps in a horizontal plane and a lid to secure the opening when the container has been filled. Our Horizontal Entry Sharps Containers, along with the Sage and Sherwood Containers also feature a wall mount bracket and a locking mechanism to secure the container, thus preventing unauthorized access or removal.

Our Horizontal Entry Sharps Container provides a receptacle for used, contaminated sharps and for enclosure during transport to ultimate disposal. The product labeling includes a cautionary statement that the "container is puncture resistant, but not entirely puncture-proof. To avoid the possibility of accidental sticks, do not overfill, inspect unit before handling and handle with care." Final disposal is typically accomplished by incineration. When incinerated in compliant medical waste incinerators, these sharps containers do not present any environmental hazards resulting from plastics combustion.

Our Horizontal Entry Sharps Container will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Daniel R. Brown
President
Custom Medical Plastics, Incorporated
14315 "C" Circle
Omaha, Nebraska 68144

JUL - 3 1997

Re: K970383
Trade Name: Sharps Container
Regulatory Class: II
Product Code: FMI
Dated: May 14, 1997
Received: May 20, 1997

Dear Mr. Brown:

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 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 requirement, 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 premarket notification submission does not affect any obligation you might have under sections 531

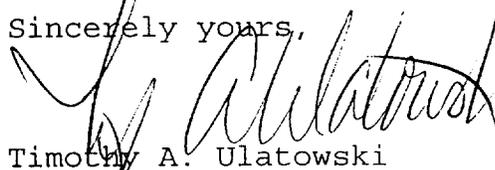
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

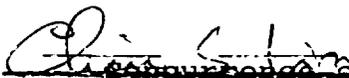
510(k) Number: K970383

Device Name: Sharps Container

Indications For Use:

Our Horizontal Entry Sharps Containers provide a receptacle for used, contaminated medical Sharps and for enclosure during transport to ultimate disposal.

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


~~Responsible for~~ Responsible for CDPH, Office of Device Evaluation (ODE)
(Division Sign-Off)

Division of **Dental, Infection Control,**
and **General Hospital Devices**

510(k) Number K970383

Prescription Use _____ OR
(Per 21 CFR 801.109)

Over-the-Counter Use X
(Optional Format 1-2-96)