

4/6/99

K982029

**American Medical Manufacturing, Inc.  
SHARPS COLLECTION CONTAINER**

**510(k) Summary**

**SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION  
UPON WHICH  
AN EQUIVALENCE DETERMINATION COULD BE BASED**

**SUBMITTER INFORMATION**

NAME:	American Medical Manufacturing	TELEPHONE:	(818) 701-7171
ADDRESS:	9410 DeSoto Avenue, Bldg. J Chatsworth, CA 91311	CONTACT:	Mike Hoftman
		DATE OF PREPARATION:	April 4, 1998

**DEVICE NAMES**

NAME:	AMMI - Sharps Collection Container – SAF-T-Shell™
COMMON/USUAL NAME:	Sharps Collection and Disposal Systems
CLASSIFICATION NAME (if known):	Accessory: Hypodermic Single Lumen Needle

**PREDICATE OR LEGALLY MARKETED DEVICES**

Baxter  
Becton Dickinson  
Pro-Tec  
Sage Products  
Devon Industries

**DEVICE DESCRIPTION**

The American Medical Manufacturing, Inc. Sharps Collection Container is an accessory to a single lumen hypodermic needle. The proposed device functions in the same manner as predicate devices in that they provide safe collection of sharps such as syringes, needles, and blades.

Device Design/Materials Used/Physical Properties: The proposed device is comprised of polypropylene plastic.

**DEVICE INTENDED USE**

The American Medical Manufacturing, Inc. Sharps Collection Container is intended for use in any situation where the disposal of medical sharps is required, such as in hospitals, doctors' offices.

**TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)**

Characteristic	AMMI	Other Devices
Lid	Translucent/Clear	Same
Mounting Brackets	Yes	Yes
Sizes	1 Quart	Multiple
Disposable	Yes	Yes
Sterility	Non-sterile	Non-sterile



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 6 1999

Mr. Mike Hoftman  
President  
American Medical Manufacturing, Incorporated  
9410 DeSoto Avenue, Unit J  
Chatsworth, California 91311

Re: K982029  
Trade Name: Sharps Collection Container - SAF-T-Shell™  
Regulatory Class: II  
Product Code: FMI  
Dated: January 22, 1999  
Received: January 28, 1999

Dear Mr. Hoftman:

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.

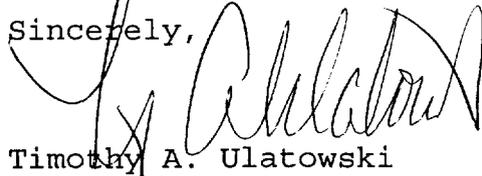
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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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) 594-4692. 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,



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 (if known): \_\_\_\_\_

Device Name: American Medical Manufacturing, Inc. Sharps Collection Container  
\_\_\_\_\_  
\_\_\_\_\_

**Indications for Use:**

The American Medical Manufacturing, Inc. Sharps Collection Container is to be used for collection and disposal of medical sharps in hospitals and doctors' offices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Paul S. Lin  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K 982029

Prescription Use \_\_\_\_\_  
(Per 21 CFR § 801.109)

OR

Over-The-Counter Use X