K980003

510(k) Summary

MAR 13 1998

Company: Imagination Medical Inc.
12855 Phillips Highway
Jacksonville, Fl. 32256
(904) 268-5531

Contact: Mr. Tim Weist

Device Name: M500-100 Sharps Container

Common Name: 1 QT Sharps Container

Classification: 21 CFR 880 Type II

The M500-100 Sharps Container was compared to the below mentioned predicate containers in that it conforms to the same standards as its predicates. This container was made from polyethylene plastic with a polyethylene locking lid. This container was molded with no side or bottom seams. The predicate devices are also made of premolded polyethylene. The M500-100 has a lid, which locks when shut preventing any leakage or loss of its contents.

The M500-100 is designed to hold up to 30 used syringes of 1cc to 5cc in size. The syringes are placed into the container in a vertical position sharp side down. Other sharps may be disposed of by dropping them into the opening at the top.

The M500-100 sharps container has a flat bottom, which makes it stable when sitting on a table. This container can also be placed in a specially designed wall bracket.

There is a black line on this container to notify the user not to overfill .

Predicate Devices:

1. B.D. Home Sharps Container K943575
2. Sage Sharps Phlebotomy Confiner # 8900MW

Conclusions of Testing:

In all test, the M500-100 sharps container met or exceeded the criteria set as pass. These test were conducted using the quidelines of the American Standards for Testing and the British Standards of Testing. This container when filled with water and allowed to stand

showed no signs of leakage from the container. With the lid locked in place and the container filled with syringes the container was dropped from a suspended string 3 feet in the air onto a hard floor. The locked lid did not open up and there were no signs of the contents spilling out or protruding through the bottom. Since syringes are placed into this container sharp side down always in a vertical position, it is unlikely that a sharp could or would protrude through the top.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 1998

Mr. Tim Weist
Director of Safety and Compliance
Imagination Medical Incorporated
12855 Phillips Highway
Jacksonville, Florida 32256

Re: K980003
Trade Name: M500-100 Sharps Container
Regulatory Class: II
Product Code: FMI
Dated: February 17, 1998
Received: February 17, 1998

Dear Mr. Weist:

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 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

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 (IF KNOWN):_K980003

DEVICE NAME:____M500-100 Sharps Container

Indications for Use:

The M500-100 sharps container is designed to hold up to 30 syringes from 1 to 5 cc in size. This container is intended for use by trained medical personnel in a medical clinic setting for the safe disposal of hazardous sharps.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Alice S. Lim

(Division Sign-Off)
Division of Dental Infection Control,
and General Hospital Devices
510(k) Number K980003

Prescription Use_____ OR Over the Counter Use_X_
(Per 21 CFR 801.109) (Optional Format 1-2-96)