



Pre-Market Notification: Sharps Shuttle
S10K Summary- K972279

AUG 29 1997

1 Identification of Applicant

- A. Company Name..... Sage Products Inc.
- B. Applicants Name..... Karen Pinto
Regulatory Affairs Manager
- C. Street Address..... 815 Tek Drive
Crystal Lake, IL 60014
- D. Address(es) of Manufacturing Site(s) .. Sage Products Inc.
815 Tek Drive
Crystal Lake, IL 60014
- E. Address(es) of Sterilizing Site(s)..... N/A-Product in non-sterile
- F. Date of Application June 17, 1997

2 Device

- A. Trade or Proprietary Name..... Sharps Shuttle/Sharps Shuttle with Locking
Mechanism
- B. Common Name..... Sharps Container
- C. Classification Name Accessory to Hypodermic Single Lumen Needle
(CFR: 880.5570)
- E. Classification..... II
- F. Panel..... 80
- G. Procodes FMI

Section 10, page 16 of 18 of Submission
Revised per 8/20/97 request

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815 TEK DRIVE ■ P.O. BOX 9693 ■ CRYSTAL LAKE, IL 60039-9693
815-455-4700 ■ 800-323-2220 ■ FAX: 815-455-5599



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3 General Description

The Sharps Shuttle and Sharps Shuttle with Locking Mechanism are injection or blow molded, single use, non-sterile, disposable, sharps transport containers intended for use in any setting where standard sharps containers are not conveniently accessible, such as EMS, home health care, etc.. The Sharps Shuttles may be viewed as a portable sharps containment device that provides an alternative to the procedure of resheathing a needle with its original protective cover which is not a recommended practice or disposing of the sharp in a non-sharps container. The products are designed to hold sharps such as angio-caths, blood needles, lancets and small syringes.

The container is cylindrical for rigidity and has a conical taper. The product body is non colored translucent plastic and is approximately 6 inches long by 1 inch in diameter. The cap is red opaque plastic with a hinged cap which when snapped closed contains the biohazardous sharps for safe conveyance.

Locking and non locking versions are available. Both versions have a temporary closure which can be reopened for the placement of additional sharps prior to terminal disposal. In addition to the temporary closure, the locking Sharps Shuttle with Locking Mechanism can be permanently locked by engaging the locking tab.

Each unit is individually labeled with a biohazard label. Sharps Shuttles are available singly or packaged in a dispenser with an attached carrying handle for easy transport of unused containers. The dispenser is available for the storage of the device prior use. The dispenser does not function as an accessory for use, nor, is it intended to transport containers with biohazardous waste.

4 Substantial Equivalence

A. Predicate Devices for Sage Products, Inc. Sharps Shuttle

- BD Home Sharps Container by Med-Safe Systems, Inc
- One Quart Sharps Container by Sage Products, Inc.
- SHARP-SAFE by Smiths Industries Medical Systems
- STIC-KIT by Emergency Medical Innovations, Inc.

B. Rationale Discussion

In summary, all five products are plastic, non-sterile, disposable, portable, sharps transport containers intended for use in various field situations. All the devices allow for one handed disposal of sharps and offer a means of closure.



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5 Design Features

Design Feature	Safety and Effectiveness Basis
Impact Resistance	The impact resistance test will provide information about the containers ability to retain solid contents, following lid closure and locking, in the event it is dropped during handling/transport.
Puncture Resistance	Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are puncture resistant. Ref: OSHA Bloodborne Pathogens 21 CFR 1910.1030, d, 4, iii, A, 1, ii
Overfill Detection	During use, containers for contaminated sharps shall be replaced routinely and not be allowed to overfill. Ref: OSHA Bloodborne Pathogens 21 CFR 1910.1030, d, 4, iii, A, 2, iii
Leak Resistance	Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are Leak Proof on sides and bottom. Ref: OSHA Bloodborne Pathogens 21 CFR 1910.1030, d, 4, iii, A, 1, iii.
Sharps Access and Closure	Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are closable. Ref: OSHA Bloodborne Pathogens 21 CFR 1910.1030, d, 4, iii, A, 1, i
Stability	During use, containers for contaminated sharps shall be maintained upright throughout use. Ref: OSHA Bloodborne Pathogens 21 CFR 1910.1030, d, 4, iii, A, 2, ii
Mounting Accessories	During use, containers for contaminated sharps shall be easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found. Ref: OSHA Bloodborne Pathogens 21 CFR 1910.1030, d, 4, iii, A, 2, i
Handling	Sharps containers should be safe and easy to handle in transport.
Capacity	This value gives the user an estimate or comparison of volume.

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 Revised per 8/20/97 request

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Karen Pinto
Regulatory Affairs Manager
Sage Products, Incorporated
815 Tek Drive
Crystal Lake, Illinois 60014-9693

AUG 29 1997

Re: K972279
Trade Name: Sharps Shuttle and Sharps Shuttle with
Locking Mechanism
Regulatory Class: II
Product Code: FMI
Dated: June 17, 1997
Received: June 18, 1997

Dear Ms. Pinto:

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.

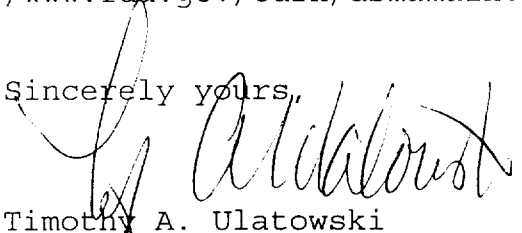
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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): K972279

Device Name: Sharps Shuttle and Sharps Shuttle with Locking Mechanism

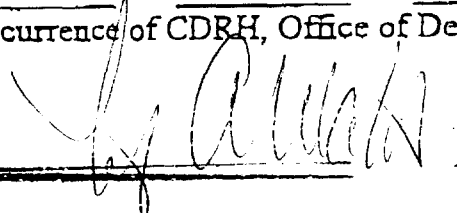
Indications For Use:

The Sharps Shuttle and Sharp Shuttle with Locking Mechanism are single use, non-sterile, disposable, sharps transport containers intended for use in any setting where standard sharps containers are not conveniently accessible, such as EMS, home health care, etc..

[Section 9, Page 15 of 18 of Response to 8/20/97 Request for Additional Information
Re: Pre-Market Notification Submission: Sharps Shuttle]

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


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

510(k) Number K972279

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)