

Pre-Market Notification: Sharps Containers with Screw Top Caps

510K Summary

K980490

815 TEK DRIVE

1 Identification of Applicant

P.O. Box 9693

- A. Company Name Sage Products Inc.
- B. Applicants Name..... Christine Falkstrom
Regulatory Affairs Associate
- 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 is non-sterile
- F. Date of Application..... February 6, 1998

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ILLINOIS

815-455-9693

2 Cover Letter

- A. Trade or Proprietary Name Sage Products, Inc. Sharps Disposal
Containers with Screw Top Caps
- B. Common Name Sharps Containers
- C. Classification Name Accessory to Hypodermic Single Lumen
Needle (CFR: 880.5570)
- D. Classification II
- E. Panel..... 80
- F. Procodes..... FMI

815-455-4700

800-323-2220

FAX 815-455-5599

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3 General Description

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The Sage Products, Inc. Sharps Containers with Screw Top Caps are molded, single use, non-sterile, disposable, sharps disposal containers. The containers are designed to hold used sharps such as angio-caths, blood needles, lancets and various sized syringes. Various sizes of the container will be offered to meet customer disposal needs. The shape of the container will either be rectangular or circular depending upon its size. The only access to the container is through the screw top closure. Products will be available with or without a neck insert at the opening to limit the ability of the sharps to exit the container after disposal.

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4 Substantial Equivalence

39-9693

A. Predicate Devices for Sage Products, Inc. Sharps Containers with Screw Top Caps

- Large Volume Sharps Container by Sage Products, Inc.
- 3 Quart Sharps Container by OnGard Systems, Inc.

B. Rationale Discussion

In summary, all products are plastic, non-sterile, disposable, sharps transport containers intended for use where medical waste is generated. All the devices allow for one handed disposal of sharps and offer a means of closure.

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5 Design Features

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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.
Mailability	Per the Domestic Mail Manual, Section 2.2, "No item may be packaged so that its contents could harm employees, equipment, or other mail."



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1998

Ms. Christine Falkstrom
Regulatory Affairs Associate
Sage® Products Incorporated
815 Tek Drive
Crystal Lake, Illinois 60014

Re: K980490
Trade Name: Sage Products Incorporated, Sharps Disposal
Containers with Screw Top Caps
Regulatory Class: II
Product Code: FMI
Dated: February 6, 1998
Received: February 9, 1998

Dear Ms. Falkstrom:

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 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 pre-market 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) 594-4692. 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 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): Unknown

Device Name: Sharps Disposal Containers with Screw Top Caps

Indications For Use:

The Sage Sharps Disposal Containers with Screw Top Caps is intended for single use disposal of used or contaminated medical sharps, including, but not limited to, hypodermic needles, syringes, lancets, and Blood Needles. The containers can be used in variety of healthcare settings. The containers are suitable for physician offices, dental offices, laboratories, home health and other generators of medical waste. The containers are also appropriate for patient room applications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chun S. Lin

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

510(k) Number K980490

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X