SAGE
PRODUCTS INC

OCT 29 1997

Pre-Market Notification: 2 Gallon Alternate Care Sharps Container
510K Summary

K973911

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 is non-sterile
F.	Date of Application	October 13, 1997

2 Device

A.	Trade or Proprietary Name	2 Gallon Alternate Care Sharps Container
B.	Common Name	Sharps Container
C.	Classification Name	Accessory to Hypodermic Single Lumen Needle (CFR: 880.5570)
D.	Classification	II
E.	Panel	80
F.	Procodes	FMI

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815-455-4700 ▪ 800-323-2220 ▪ Fax: 815-455-5599

3 General Description

The Sage 2 Gallon Alternate Care Sharps Container is an injection molded, single use, non-sterile, disposable, sharps disposal container. The product is designed to hold sharps such as angio-caths, blood needles, lancets and various sized syringes and non-sharps such as drug infusion cassettes.

4 Substantial Equivalence

A. Predicate Devices for Sage Products, Inc. 2 Gallon Alternate Care Sharps Container

- 2 Gallon Sharps Container with Hinged Lid and Rotor #8535 by Sage Products, Inc.
- 5 Quart Sharp Star #8508 by Sage Products, Inc.
- 2 Quart Sharps Disposal Container #1522 by Sage Products, Inc.

B. Rationale Discussion

In summary, all four products are plastic, non-sterile, disposable, sharps transport containers. 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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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 29 1997

Re: K973911
Trade Name: 2 Gallon Alternate Care Sharps Container
Regulatory Class: II
Product Code: FMI
Dated: October 13, 1997
Received: October 14, 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): Unknown

Device Name: 2 Gallon Alternate Care Sharps Container

Indications For Use:

The Sage 2 Gallon Alternate Care Sharps Container is intended for single use disposal of used or contaminated medical sharps, including, but not limited to, hypodermic needles, syringes, lancets, IV Cassettes, and Blood Needles. Sage 2 Gallon Alternate Care Sharps Containers are used in both clinical and non-clinical settings.

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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)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973911

Prescription Use ____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)