



K972705

Appendix H

**510(k) SUMMARY - Resheathing Devices**

**GENERAL:** Establishment Name/ Manufacturing Site Sage Products, Incorporated  
815 Tek Drive  
Crystal Lake, IL 60039-9693

Contact Person Karen Pinto, Regulatory Affairs Manager

Telephone (815) 455-4700 ext.1383

Fax Number (815) 455-5599

**IDENTIFICATION:** Trade Name Resheathing Devices

Common Name Resheather /Needle Holder

Classification Name FMI

**SUBSTANTIAL EQUIVALENCE:**

The Sage Products Inc. Resheathing Devices are similar in intended use/substantially equivalent to the following predicate devices:

<b>MANUFACTURER</b>	PEPCO	On-Gard Systems Inc.
<b>PRODUCT</b>	NeedleGard II™	On-Gard Systems® Recapper

**DESCRIPTION:**

The Resheathing Devices are constructed of metal or plastic, can be placed securely at or near the point of use and enable the healthcare worker to single handedly recap, or hold a hypodermic syringe, blood collection device, or IV administration set.

**INTENDED USE:**

The plastic and metal resheathers are placed at or near the point of use and allow one handed needle resheathing. The plastic and foam resheather/needle holder is placed at or near the point of use and allows one handed needle resheathing or allows the user to place the needle into the foam to temporarily hold it prior to disposal.

**TECHNOLOGICAL CHARACTERISTICS:**

The Sage Products Inc. Resheathing Devices are similar in their technological characteristics to their predicate devices. The Resheathing Devices are able to accommodate varying sizes of needle sheaths, and can be mounted to surfaces for stabilization.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 30 1998

Ms. Karen Pinto  
Regulatory Affairs Manager  
Sage Products, Incorporated  
815 Tek Drive  
Crystal Lake, Illinois 60039-9693

Re: K972705  
Trade Name: Sage Resheathers, Needle Resheather/Holder  
Regulatory Class: II  
Product Code: FMI  
Dated: April 7, 1998  
Received: April 8, 1998

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 (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

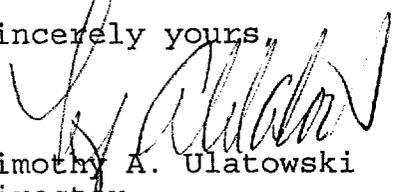
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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): K972705

Device Name: Needle Resheather, Needle Resheather/Holder

Indications For Use:

The plastic and metal resheathers are placed at or near the point of use and allow one handed needle resheathing. The plastic and foam resheather/needle holder is placed at or near the point of use and allows one handed needle resheathing or allows the user to place the needle into the foam to temporarily hold it prior to disposal.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number \_\_\_\_\_

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

OR

Over-The-Counter Use \_\_\_\_\_