DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 1 2006

SAGE Products, Inc.
c/o Ms. Karen Pinto
Regulatory Affairs Manager
815 Tek Drive, P.O. Box 9693
Crystal Lake, Illinois 60039-9693

Re: K972302
Trade/Device Name: Pocket Count or SafeTCount
Regulation Number: 21 CFR 880.2740
Regulation Name: Surgical sponge scale
Regulatory Class: I Exempt
Product Code: LWH
Dated: June 18, 1997
Received: June 19, 1997

Dear Ms. Pinto:

This letter corrects our substantially equivalent letter of July 25, 1997.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

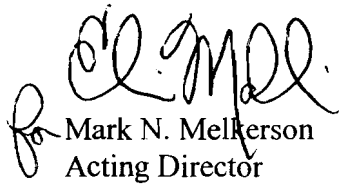
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21

CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K972302

SAGE PRODUCTS INC

JUL 25 1997

17 510(k) Summary

Company Name	Sage Products Inc.
Street Address	815 Tek Drive, Crystal Lake, IL 60014
Date of Summary Preparation	June 18, 1997
Device Name	
Trade or Proprietary Name	Pocket Count or SafeTCount
Common Name	Surgical Sponge Counter (CFR designation does not exist)
Classification Name	Sponge Counter
Intended Use	Containment and Counting of Sponges
Description	
Pocket Count	Transparent, compartmentalized, disposable bag which allows visual confirmation of sponge count and visual estimate of absorbed fluid. Pocket Count provides partial containment of contaminated sponges, thereby, decreasing worker exposure to contents.
SafeTCount	Transparent, disposable hand shaped covering which is used to collect sponges. When the covering is turned inside out it contains the contaminated sponges, thereby, decreasing worker exposure to contents. The SafeTCount allows visual confirmation of sponge count and visual estimate of absorbed fluid.

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

17 510(k) Summary (Continued)

Substantial Equivalence Comparison

Product Name	Pocket Count	Bag-It	SafeTCount	Multi-Mitt
Manufacturer	**Sage Products**	**Devon**	**Sage Products**	**Devon**
Intended Use of Product	Containment and counting of sponges	Containment and counting of sponges	Containment and counting of sponges	Containment and counting of sponges
Design	compartmentalized pockets	compartmentalized pockets	hand shaped hand covering	rectangular hand covering
Pull Tabs	Available	Not available	N/A	N/A
Material	Polyethylene	Polyethylene	Polyethylene	Polyethylene
Clarity	Transparent	Transparent	Transparent	Transparent
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Target Population	OR/Hospital	OR	OR/Hospital	Hospital
Compliance with Standards	N/A	N/A	21 CFR 800.20	21 CFR 800.20
Performance	Holds up to 5 lap sponges or 10 - 4x4's	Holds up to 5 lap sponges or 10 - 4x4's	Holds up to 5 lap sponges or 10 - 4x4's	No Claim Made
Accessories Available	Bracket for mounting	Bracket for mounting	Bracket for mounting	Bracket for mounting

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510(k) Number (if known): K97 2302

Device Name: Sponge Counter

Indications For Use:

Containment and Counting of Sponges in the Operating Room or a hospital setting.

Section 16, page 11 of 13 of submission

(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 General Restorative Devices
510(k) Number K972302

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

(Optional Format 1-2-96)