

JAN 29 1998

K 973981

510(k) Summary

- a(1) Submitted by: Adroit Medical Systems, Inc.
1146 Carding Machine Rd.
Loudon, TN 37774
423-458-8600
- Contact Person: Richard L. Studer
423-458-8600
- Prepared on: October 10, 1997
- a(2) Proprietary Name: **SafePASS** Sterilization Pouch
Common Name: Sterilization Bag
Classification Name: Sterilization Wrap
- a(3) Adroit Medical Systems, Inc. believes that **SafePASS** Sterilization Pouches are substantially equivalent to the various sizes of SupraShield hospital sterilization wrap, 510(k) number K921243, marketed by V. Mueller, a division of Allegiance Healthcare Corporation (formerly a division of Baxter International Corporation).
- a(4) **SafePASS** Sterilization Pouches are pouches made of previously 510(k) cleared sterilization wrap material. **SafePASS** Sterilization Pouches are provided to the end user in a partially folded condition, representing the first step of a patented folding system. After inserting the item or items to be sterilized, the pouch is closed by making the final two folds as described in the instructions for use. Once closed in this method and sterilized, the pouch allows convenient aseptic presentation of the enclosed device by following that section of the instructions for use.
- SafePASS** Sterilization Pouches are provided in both single and double thickness versions.
- Included in this section is the draft labeling and instructions for use.
- a(5) **SafePASS** Sterilization Pouches are intended for use as sterility barrier packaging in the steam sterilization of various medical devices, kits, instruments, etc.
- a(6) **SafePASS** Sterilization Pouches are manufactured using the same material that is used to produce the SupraShield Sterilization Wrap product.

The difference is how the finished device is presented to the end user. For a **SafePASS** Sterilization Pouch, a sheet of material is folded over and sealed along two edges forming a pouch. This pouch then has a portion of the open end folded concentrically back over itself, thereby forming a cuff. From this point, the user inserts the item or items to be sterilized and closes the pouch by making the final two folds as instructed in

the directions for use. The SupraShield Sterilization Wrap is provided to the end user as a flat sheet with the user folding it around the item to be sterilized as desired.

In some situations it is desired that two layers of sterilization wrap be used. For those situations *SafePASS* Sterilization Pouches will be available in both a single thickness and a double thickness version.

- b This section is not required for this submission because substantial equivalence is based on intended use and device characteristics and specifications, and not on an assessment of performance data.

Draft Carton Labeling

Size, Reorder No., and Contents Qty. modified for specific products

SafePASS TM

Sterilization Cover
&
Presentation System
For Steam Sterilization Only

Reorder Number 1211R

Size - 12" x 11"
Reinforced
Contents 100 each

Manufactured by:
Adroit Medical Systems
1146 Carding Machine Road
Loudon, TN 37774
423-458-0880

U.S. Patent No. 5,638,661

SafePASS™

SafePASS Sterilization Pouches are intended for use as sterility barrier packaging in the steam sterilization of various medical devices, kits, instruments, etc.

SIZING GUIDELINES

1. Measure the circumference of the longest dimension and divide by 2.

Example: An item where the longest dimension is 22" in circumference would require a **SafePASS™** that is at least 12" wide; 22 divided by 2 equals 11.

2. Measure the circumference of the shortest dimension and divide by 2.

Example: An item where the shortest dimension is 20" in circumference would require a **SafePASS™** that is at least 10" wide; 20 divided by 2 equals 10.

The most efficient **SafePASS™** for this example would be model 1211 or 1211R

PACKAGING INSTRUCTIONS

1. Place item to be sterilized inside pre-cuffed **SafePASS™** with the longest dimension positioned sidewise from left to right. Ensure that the top of the item to be sterilized does not extend past the "DO NOT FILL PAST THIS LINE" line.
2. Place **SafePASS™** with label side down and the open end facing toward you.
3. Fold open end back so that the "TUCK THIS LINE UNDER CUFF" line is past the edge of the cuff.
4. Secure by tucking open end underneath cuff past the "TUCK THIS LINE UNDER CUFF" line.
5. Complete by applying CSR tape across locking fold.

ASEPTIC PRESENTATION INSTRUCTIONS

1. Remove CSR tape across locking fold by pulling downward.

2. Turn package over and hold with dominant hand.
3. Position thumb of dominant hand and hold *SafePASS*™ as indicated on label.
4. Locate edge of cuff between thumb and forefingers of free hand.
5. Slide free hand along edge of the cuff to the far end of either side.
6. Grasp the cuff between thumb and forefingers and pull firmly downward towards you.
7. Release grip and slide free hand along edge of the cuff to the opposite side.
8. At opposite end , grasp cuff between thumb and forefingers and pull firmly downward towards you.
9. Repeat this pulling motion by alternating from side to side with your free hand until the “locking fold” releases.
10. As the “locking fold” releases, fully extend *SafePASS*™ by pulling downward to invert over the hand and forearm holding the package.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1998

Mr. Richard L. Studer
Adroit Medical Systems, Incorporated
1146 Carding Machine Road
Loudon, Tennessee 37774

Re: K973981
Trade Name: SafePass Sterilization Pouch
Regulatory Class: II
Product Code: KCT
Dated: December 1, 1997
Received: December 3, 1997

Dear Mr. Studer:

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.

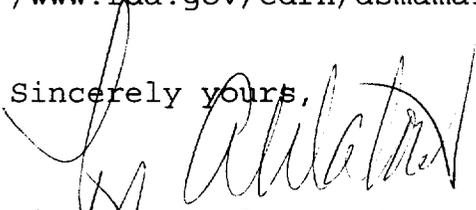
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 K973981

Indications For Use:

SafePASS Sterilization Pouches are intended for use as sterility barrier packaging in the steam sterilization of various medical devices, kits, instruments, etc.

A **SafePASS Sterilization Pouch** is intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

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

Chin S. Lim
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973981

Prescription Use _____

OR

Over - The Counter Use X

(Per 21 CFR 801.109)

(Optional Format 1-2-96)