K022441

510(k) SUMMARY

Applicant's Name, Address, Telephone, FAX, Contact Person
Advanced Sterilization Products
Division of Ethicon, Inc.
33 Technology Drive
Irvine, CA 92618

Contact Person
Natalie Bennington
Senior Regulatory Affairs Specialist
Tel: (949) 453-6482
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September 12, 2002

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Common/Usual Name: Chemical Indicator
Product Classification: Physical / Chemical Sterilization Process Indicator, Class II
Proprietary Name: STERRAD® SealSure™ Chemical Indicator Tape

PREDICATE DEVICE

The predicate device is the STERRAD® Chemical Indicator Tape for use in the STERRAD® Sterilization Systems, currently manufactured and distributed by Advanced Sterilization Products.

INDICATIONS-FOR-USE

STERRAD® SealSure™ Chemical Indicator Tape is a process indicator intended for use by health care providers to secure non-woven sterilization packs and wraps to be sterilized in the STERRAD® Sterilization System.

The color of the STERRAD® SealSure™ Chemical Indicator Tape changes from red to gold (or lighter) when exposed to hydrogen peroxide and is intended to differentiate between processed and unprocessed loads. Reference the color comparator bars on the package box label.

DEVICE DESCRIPTION

STERRAD® SealSure™ Chemical Indicator Tape (Class A per EN867-1 and Class 1 ISO 11140-1) is a through-put process indicator tape to be used with ASP's STERRAD® Sterilization System. STERRAD® SealSure™ Chemical Indicator Tape offers an additional way to verify processing in the sterilization cycle. It should be used in addition to, not in place of, the biological indicator. STERRAD® SealSure™ Chemical Indicator Tape does not signify sterilization; it only indicates that the indicator has been exposed to hydrogen peroxide.

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There are six rolls of STERRAD® SealSure™ Chemical Indicator Tape per box. Each roll contains 55 meters (60 yards) of indicator tape.

COMPARISON TO THE PREDICATE DEVICE

STERRAD® SealSure™ Chemical Indicator Tape for use in the STERRAD® Sterilization System is substantially equivalent to STERRAD® Chemical Indicator Tape also for use in the STERRAD® Sterilization System. These devices are intended for use by health care providers to secure non-woven sterilization wraps used on medical devices to be sterilized in the STERRAD® Sterilization System and to differentiate processed from unprocessed items. In addition, both of these devices share similar design and appearance.

VALIDATION STUDIES

1. **Functionality Study of the STERRAD® SealSure™ Chemical Indicator Tape in STERRAD® Sterilization Systems**
   The functionality of STERRAD® SealSure™ Chemical Indicator Tape was tested in each of the STERRAD® Sterilization Systems. Functionality was verified as all tape samples changed from red to yellow at half-cycle conditions.

2. **Effects of Chemicals, Air Plasma and Shipping Temperature on STERRAD® SealSure™ Chemical Indicator Tape for use in the STERRAD® Systems**
   The effects of chemicals, air plasma and shipping temperature on STERRAD® SealSure™ Chemical Indicator Tape for use in the STERRAD® Sterilization Systems were tested.

   The test results demonstrated that STERRAD® SealSure™ Chemical Indicator Tape has adequate resistance to chemicals, with exception of organic solvents with high polarity as well as strong acids. STERRAD® SealSure™ Chemical Indicator Tape also has the ability to distinguish between a processed load vs. a load in which the cycle was cancelled prior to exposure to the hydrogen peroxide. Lastly, it was shown that STERRAD® SealSure™ Chemical Indicator Tape maintained its stability in a simulated shipping environment.

3. **Color and Functionality Stability Studies of Pre and Post-processing STERRAD® SealSure™ Chemical Indicator Tape Samples (Unopened Package)**
   Shelf life color stability studies were conducted for both pre-processed and post-processed samples of STERRAD® SealSure™ Chemical Indicator Tape. In addition, a functionality stability study was also performed on the pre-processed samples.
   The test results demonstrated that the pre-processed samples maintained the pre-processing color and functionality at both ambient and accelerated aging conditions for four months. In addition, the post-processed tape samples retained their post-processing color after aged in both ambient and accelerated aging conditions for two months.

4. **Color and Functionality Stability Studies of Pre and Post-processing STERRAD® SealSure™ Chemical Indicator Tape Samples (Opened Package)**
   The color and functionality stability of opened-package STERRAD® SealSure™ Chemical Indicator Tape samples stored in two ambient conditions were tested. The first ambient

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condition was used to simulate a hospital's sterilizer room and the other was used to simulate the storage room of the central supply area (CS Department).

The stability of post-processed tape samples stored in a storage room condition was also evaluated.

The results of this study demonstrated that the color and functionality stability of the pre-processed tape samples were maintained in each ambient condition for one month. In addition, the post-processing color was stable for one month. The pre-processed color and functionality stability studies will continue for a total of two months.

5. **Efficacy Testing of STERRAD® Sterilization System with excess amount of STERRAD® SealSure™ Chemical Indicator Tape**
The efficacy of using an extreme amount of STERRAD® SealSure™ Chemical Indicator Tape on each validation tray in each of the STERRAD® Sterilization Systems was tested. Complete inactivation of challenge microorganisms in the defined test configuration was achieved in each System.

The test results demonstrated that the effect on sterilization efficacy of each of the STERRAD® Systems is insignificant, regardless of using an extreme amount of chemical indicator tape on each validation tray.

6. **Adhesion Strength and Stability of the STERRAD® SealSure™ Chemical Indicator Tape for use in the STERRAD® Systems**
The adhesion strength and stability of STERRAD® SealSure™ Chemical Indicator Tape was tested.

The test results demonstrated that STERRAD® SealSure™ Chemical Indicator Tape meets the minimum adhesion strength requirements. Stability testing results also demonstrated the maintenance of the minimum adhesion strength over three months in accelerated and room temperature aging environments.

CONCLUSION

Results of the validation studies demonstrate that the STERRAD® SealSure™ Chemical Indicator Tape meet or exceed all functional requirements and support its suitability for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2002

Ms. Natalie Bennington
Senior Regulatory Affairs Specialist
Advanced Sterilization Products
Division of Ethicon, Incorporated
33 Technology Drive
Irvine, California 92618

Re: K022441
Trade/Device Name: STERRAD® Sealsure™ Chemical Indicator Tape
Regulation Number: 21 CFR 880.2800
Regulation Name: Chemical Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: July 24, 2002
Received: July 25, 2002

Dear Ms. Bennington:

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 application (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 such 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 begin 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ADVANCED STERILIZATION PRODUCTS℠
a Johnson & Johnson company
REGULATORY AFFAIRS DEPARTMENT

510(k) Number (if known): K022441

Device Name: STERRAD® SealSure™ Chemical Indicator Tape

Indications-For-Use:

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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)

Prescription Use _____ **OR** **Over-The-Counter Use**
(PER 21 CFR 801.109)

(Optional Format 1-2-96)

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

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