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

K040742

510(k) Summary

Applicant's Name, Address, Telephone, FAX, Contact Person

Advanced Sterilization Products
A Division of Johnson & Johnson Medical, Inc.
33 Technology Drive
Irvine, CA 92618

Contact Person

Kevin Corrigan, R.A.C.
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Submission Date

March 22, 2004

Trade Name

STERRAD® SealSure™ Chemical Indicator Tape

Common Name

Chemical Sterilization Process Indicator

Classification Name

Class II

Legally Marketed Equivalent Device Name(s)

STERRAD® SealSure™ Chemical Indicator Tape, K022441, October 8, 2002.

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Description of Device

STERRAD® SealSure™ Chemical Indicator Tape is a through-put process indicator tape to be used with ASP's STERRAD® Sterilization Systems. The STERRAD® Sterilization System utilizes hydrogen peroxide gas plasma to achieve rapid, low temperature sterilization of medical devices.

STERRAD® SealSure™ Chemical Indicator Tape is not intended to imply that sterilization has been achieved or to assure that the sterilization cycle has been completed. Rather, it provides a visual indication that hydrogen peroxide, an essential ingredient in the operation of the STERRAD® Sterilization Process, is present in the sterilization chamber.

STERRAD® SealSure™ Chemical Indicator Tape functions by means of a chemical reaction. Exposure of the chemical indicator to the STERRAD® Sterilizer cycle results in a recognizable color change from red to yellow. The gold (or lighter) STERRAD logos and chemical indicator square indicate that the load has been exposed to hydrogen peroxide.

Statement of Intended Use

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

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.

Description of Modification

The modification is to the methods used to test the product for final release. Additionally, the labeling for the device was modified to reflect this release testing and to extend the shelf life of the device.

Summary of Nonclinical Tests

Unopened package shelf life stability studies were conducted on samples of SealSure Chemical Indicator Tape to assess the color and functionality throughout the shelf life of the product. Based upon the results obtained, the study supports an extension of the unopened package shelf life to 22 months.

Opened package shelf life stability studies were conducted on samples of SealSure Chemical Indicator Tape to assess the color and functionality throughout the shelf life of the product. Based upon the results obtained, the study supports an extension of the opened package shelf life to 5 months.

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Adhesion Strength studies were conducted on samples of SealSure Chemical Indicator Tape to assess the adhesive properties of the tape at the end of the labeled shelf life for the product. Based upon the results obtained, the study confirms that the tape has adequate preprocessing and post-processing adhesive properties to support an extension of the product to 22 months.

Substantial Equivalence

The modified STERRAD® SealSure Chemical Indicator Tape has the following similarities to that which previously received 510(k) clearance:

- has the same intended use,
- have the same indicated use,
- use the same operating principle,
- incorporate the same design,
- uses the same fundamental scientific technology,
- incorporate the same materials and construction and
- is packaged using the same materials and processes.

In summary, the STERRAD® SealSure Chemical Indicator Tape described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2004

Advanced Sterilization Products
Mr. Kevin Corrigan
Manager of Regulatory Affairs
A Division of Johnson & Johnson Medical, Incorporated
33 Technology Drive
Irvine, California 92618

Re: K040742
Trade/Device Name: Modification to Sterrad® SealSure™ Chemical Indicator Tape
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indication
Regulatory Class: II
Product Code: JOJ
Dated: March 22, 2004
Received: March 23, 2003

Dear Mr. Corrigan:

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.

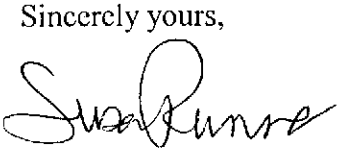
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-5618. 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,



for Chiu Lin, Ph.D.
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

Indications for Use

510(k) Number: K040742

Device Name STERRAD® SealSure™ Chemical Indicator Tape

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.

Prescription Use _____ OR Over-the-Counter Use X

(Optional Format 1-2-96)

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

510(k) Number: K040742