K111519

p. 1 of 3

OCT 3 2012

510(k) Summary

Applicant's Name, Address, Telephone, FAX, Contact Person
Advanced Sterilization Products,
33 Technology Drive
Irvine, CA 92618

Contact Person
Nancy Chu
Manager, Regulatory Affairs
(949) 453-6435 Telephone
(949) 789-3900 Fax

Date: September 10, 2012

1. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Sterilization Process Indicator
Common/Usual Name:	Chemical Sterilization Process Indicator
Product Classification:	II
Proprietary Name:	STERRAD® SEALSURE® Chemical Indicator Tape

2. PREDICATE DEVICES

STERRAD® SEALSURE® Chemical Indicator Tape (K103219)

3. INDICATIONS FOR USE

STERRAD® SEALSURE® Chemical Indicator Tape (PN 14202) is a process indicator (ISO 11140-1:2005) intended for use by healthcare providers to secure non-woven sterilization packs and wraps to be sterilized in the STERRAD® Sterilization Systems.

MODEL	CYCLE
STERRAD® 100S	Standard
STERRAD® 50	Standard
STERRAD® 200	Standard
STERRAD® NX®	Standard
	Advanced
STERRAD®100NX®	Standard
	Flex
	EXPRESS
	DUO

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.

4. DESCRIPTION OF DEVICE

STERRAD® SEALSURE® Chemical Indicator Tape is a process indicator intended for use by healthcare 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.

5. SUMMARY OF NONCLINICAL TESTS

Performance testing was conducted to demonstrate the functionality of STERRAD® SEALSURE® Chemical Indicator Tape in the STERRAD® 100NX® DUO Cycle and the results show that the STERRAD® SEALSURE® Chemical Indicator Tape performs as a through-put process indicator by responding to hydrogen peroxide exposure. Product shelf-life was presented in the STERRAD® SEALSURE® Chemical Indicator Tape, EXPRESS cycle 510(k) submission (K103219) and was not repeated nor presented in this submission since the product's design has not changed.

STUDY	RESULTS
Chemical Indicator Functionality	Passed
Tape Adhesion Strength	Passed
End Point / Post Processing Color Stability	Passed
Biocompatibility	Passed
Shelf life	Passed

6. OVERALL PERFORMANCE CONCLUSIONS

The nonclinical studies demonstrate that the STERRAD® SEALSURE® Chemical Indicator Tape is as safe and as effective for differentiating processed from unprocessed packages when used with the STERRAD® 100NX® DUO Cycle, and within the indications for use for the indicator and tape, thus establishing that the STERRAD® SEALSURE® Chemical Indicator Tape is substantially equivalent to the predicate device, the STERRAD® SEALSURE ® Chemical Indicator Tape (K103219, cleared 4/1/2011).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 3 2012

Advanced Sterilization Products
Ms. Nancy Chu
Manager, Regulatory Affairs
33 Technology Drive
Irvine, California 92618

Re: K111519
Trade/Device Name: Sterrad® Sealsure® Chemical Indicator Tape (PN 14202)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: September 21, 2012
Received: September 24, 2012

Dear Ms. Chu:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111519

Device Name: STERRAD® SEALSURE® Chemical Indicator Tape

Indications for Use
STERRAD® SEALSURE® Chemical Indicator Tape (PN 14202) is a process indicator (ISO 11140-1:2005) intended for use by healthcare providers to secure non-woven sterilization packs and wraps to be sterilized in the STERRAD® Sterilization Systems.

MODEL	CYCLE
STERRAD® 100S	Standard
STERRAD® 50	Standard
STERRAD® 200	Standard
STERRAD® NX®	Standard
	Advanced
STERRAD®100NX®	Standard
	Flex
	EXPRESS
	DUO

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.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use √ (21 CFR 801 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111519

(Posted November 13, 2003)