STERIS®

K070461

510(k) Summary
For
Verify® Steam Indicators

JUL 17 2007

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Date Prepared: June 12, 2007

1. Device Name

Indicators Models:	Verify® 250°F 30 Indicator Verify® 270°F 15 Indicator Verify® 270°F 3-10 Indicator Verify® 270°F 4 Indicator
Common Name:	Chemical Indicator
Classification Name:	Physical/chemical sterilization process indicator (21 CFR 880.2800 (b), Product Code JOJ).

2. Predicate Devices

- 3M SteriGage Chemical Indicators
- DANA SteriScan Indicators
- SteriTec Integraph (Cardinal Steam Integrators[1])
- STERIS Verify Integrators

3. Device Description

The proposed Verify® Steam Indicators consist of a 22mm x 143 mm strip (7/8" x 5.6") with a 12 mm circular chemical indicator ink spot (or two spots in the case of the 270°F 3-10 Indicator) located on one end, adjacent to a reference circle exhibiting the endpoint color. The indicator ink on the proposed Verify® Steam Indicators changes from yellow to blue/purple color when the steam sterilization cycle is complete.

- The Verify® 250°F 30 Indicator can be used to monitor a 30 minute 250°F/121°C gravity steam sterilization cycle.
- The Verify® 270°F 15 Indicator can be used to monitor a 15 minute 270°F/132°C gravity steam sterilization cycle.
- The Verify® 270°F 3-10 Indicator can be used to monitor a 3 minute or10 minute 270°F/132°C gravity flash steam sterilization cycle.
- The Verify® 270°F 4 Indicator can be used to monitor a 4 minute 270°F/132°C SFPP, pre-vacuum and Express steam sterilization cycle.

[1] Cardinal is a private label brand produced by Steritec under K960441.

4. Intended Use

The Verify® Steam Indicators are chemical indicators intended for use by health care providers to accompany products being sterilized through a sterilization procedure. The indicators change color from yellow to blue/purple when exposed to the proper time and temperature of the designated steam sterilization cycle. The performance of the Verify® Steam Indicators meets the requirements of ANSI/AAMI / ISO 11140-1:2005 for emulating [Class 6] steam indicators.

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are all single use indicators for use in steam sterilization cycles. The differences between the proposed bundled Verify® Steam Indicators and predicate devices are limited to differences in design, material, and parameters of the sterilization cycles these indicators are designed to monitor. These differences do not raise any new issues of safety and efficacy.

6. Performance Testing

Performance testing was conducted to verify that the proposed indicators meet the requirements for emulating [Class 6] indicators as defined in ANSI/AAMI ISO 11140-1:2005 using a resistometer to ANSI/AAMI ISO 18472.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2007

Mr. John Scoville
Regulatory Affairs Sterilization Technology
Steris Corporation
5960 Heisley Road
Mentor, Ohio 44060

Re: K070461
Trade/Device Name: Verify® Steam Indicators
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: June 22, 2007
Received: June 26, 2007

Dear Mr. Scoville:

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.

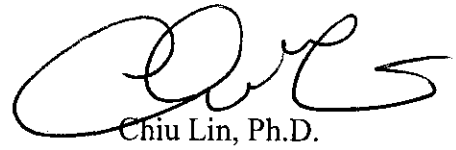
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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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): K070461

Device Name: Verify® Steam Indicators

Indications For Use:

The Verify® Steam Indicators are emulating indicators intended for use in steam sterilization. The Verify® Steam Indicators change color from yellow to blue/purple when exposed to the appropriate cycle temperature, type, and duration. The indicator models and their cycle temperatures, types, and times are:

MODEL	TEMPERATURE	STERILIZATION TYPE	TIME
Verify 250F 30	250°F (121°C)	gravity steam	30 minutes
Verify 270F 15	270°F (132°C)	gravity steam	15 minutes
Verify 270F 3-10	270°F (132°C)	gravity flash steam	3 or 10 minutes
Verify 270F 4	270°F (132°C)	Steam Flush Pressure Pulse (SFPP), pre-vacuum and Express steam	4 minutes

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (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 K070461