STERIS®

MAR 10 2011

510(k) Summary
For
Verify® 270FP Challenge Pack

STERIS Corporation
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Contact: Robert Sullivan
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Submission Date: March 10, 2011

1. Device Name

Indicator Pack Model:	Verify® 270FP Challenge Pack
Common Name:	Chemical Indicator
Classification Name:	Physical/chemical sterilization process indicator (21 CFR 880.2800 (b), Product Code JOJ).

2. Predicate Device

- STERIS Verify® Challenge Pack (Model 270F 4) – K073683
- Getinge ChemSix Test Pack – K080136

3. Device Description

The proposed Verify® 270FP Challenge Pack consists of three emulating indicator inks situated on a test sheet surrounded by a steam penetration barrier. The indicator inks on the proposed Verify® 270FP Challenge Pack test sheet change from yellow to blue/purple color when exposed to saturated steam at 270°F (132°C) for the following times.

- 4 minute indicator – The 4 minute indicator ink on the Verify® 270FP Challenge Pack can be used to monitor a 4 minute SFPP (steam-flush pressure-pulse) and pre-vacuum steam sterilization cycle.
- 10 minute indicator – The 10 minute indicator ink on the Verify® 270FP Challenge Pack can be used to monitor a 10 minute pre-vacuum steam sterilization cycle.
- 20 minute indicator – The 20 minute indicator ink on the Verify® 270FP Challenge Pack can be used to monitor a 20 minute pre-vacuum steam sterilization cycle.

The process indicator outside of the packs undergoes a visual color change from pink to dark purple when exposed to steam in a temperature range of 250°F (121°C) to 275°F (135°C).

4. Intended Use

The Verify® 270FP Challenge Pack is a test pack consisting of three emulating indicator inks situated on a test sheet surrounded by a steam penetration barrier,

intended for use in SFPP (steam-flush pressure-pulse) and pre-vacuum steam sterilization. The Verify® 270FP Challenge Pack indicators change color from yellow to blue/purple when exposed to the following conditions at 270°F (132°C):

- 4 minute indicator - SFPP and pre-vacuum steam sterilization for 4 minutes.
- 10 minute indicator - Pre-vacuum steam sterilization for 10 minutes.
- 20 minute indicator - Pre-vacuum steam sterilization for 20 minutes.

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are all single use indicator test packs for use in steam sterilization cycles. The differences between the proposed Verify® 270FP Challenge Pack and predicate devices are limited to differences in design, materials and parameters of the sterilization cycles these indicator test packs are designed to monitor. These differences do not raise any new issues of safety or efficacy.

6. Performance Testing

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

Further testing was conducted to demonstrate the efficacy of the barrier material using a 16-towel test pack with biological indicators as a reference. The predicate test packs were included in this testing.

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

Mr. Robert Sullivan
Senior Director, Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

MAR 10 2011

Re: K103053
Trade/Device Name: Verify® 270FP Challenge Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: February 4, 2011
Received: February 7, 2011

Dear Mr. Sullivan:

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.

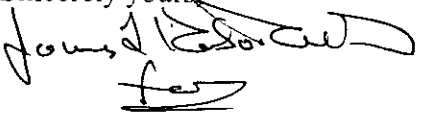
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



Anthony 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):

Device Name: Verify® 270FP Challenge Pack

Indications For Use:

The Verify® 270FP Challenge Pack is a test pack consisting of three emulating indicator inks situated on a test sheet surrounded by a steam penetration barrier, intended for use in SFPP (steam-flush pressure-pulse) and pre-vacuum steam sterilization. The Verify® 270FP Challenge Pack indicators change color from yellow to blue/purple when exposed to the following conditions at 270°F (132°C):

- 4 minute indicator - SFPP and pre-vacuum steam sterilization for 4 minutes.
- 10 minute indicator - Pre-vacuum steam sterilization for 10 minutes.
- 20 minute indicator - Pre-vacuum steam sterilization for 20 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)

Page 1 of 1

Elizabeth D. Claverie-Williams
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K103053