MAR 1 6 2009

1. Device Name

Trade Name:	Verify® V24 Self-Contained Biological Indicator
Common/usual Name:	Biological Indicator (BI)
Classification Name:	Indicator, Biological Sterilization Process (21 CFR 880.2800, FRC).

2. Predicate Device

- Verify® Self-Contained Biological Indicator for Vaporized VH2O2 Sterilization Processes, K073244, May 28, 2008
- STERRAD® Cyclesure™ Biological Indicator, K994055, Feb 13, 2002
- STERRAD® Cyclesure Biological Indicator, K031226, May 2, 2003
- STERRAD® Cyclesure Biological Indicator, K071014 May 24, 2007

3. Description of Device

The Verify V24 Self-Contained Biological Indicator (SCBI) is used by healthcare providers to monitor the Amsco® V-PRO™ 1 Low Temperature Sterilizer. It is designed to accompany medical devices placed in the sterilizer.

The user places the packaged Verify V24 SCBI into the V-PRO 1 Low Temperature Sterilization System and performs a sterilization cycle. After cycle completion, the SCBI can either be immediately activated or it can be held at room temperature for a maximum of 72 hours (3 days) prior to activation.

The SCBI is activated by sealing the vial and rupturing the medium ampoule using the STERIS Verify SCBI HP activator. The activator automatically seals the SCBI vial and releases the growth media.

The activated SCBI is incubated at 55 – 60 °C.. The SCBI indicates a pass if the media remains orange and non-turbid. The SCBI indicates a failure of sterilization if the media changes from orange to yellow and/or if the media is turbid.

The modified Verify V24 Self-Contained Biological Indicator is identical in design to the original K073244 device with exception of the media formulation. It is identical with respect to performance specifications with exception of the incubation time.

4. Intended Use

The Verify V24 Self-Contained Biological Indicator is intended as a standard method for frequent monitoring of the Amsco V-PRO 1 Low Temperature Sterilization System.

5. Description of Modification

The culture media has been modified to achieve a 24 hour incubation time and the device labeling has been modified to reflect the change in incubation period as well as a change in the media color.

6. Description of Safety and Substantial Equivalence

The Verify V24 Self-Contained Biological Indicator has the same or similar intended use, accessories, viable population, resistance characteristics, culture conditions, primary and secondary packaging, and storage conditions as compared to its predicate devices the Verify® Self-Contained Biological Indicator for Vaporized VII2O2 Sterilization Processes and STERRAD CycleSure Biological Indicator.

Summary of nonclinical tests performed to confirm the performance of the modified culture media:

Test	Result
Growth Inhibition Testing & Effect of Sterilization Process on Recovery Media	Pass There was no growth inhibition and no effect of the sterilization process on the media.
Incubation Time Validation	Pass 24 hour Incubation
Media Performance Evaluations	Pass All viability control SCBIs displayed growth within 24 hrs. Media was present and the color remained yellow for 7 days. All uninoculated SCBIs were sterile and the media remained orange for 7 days
Media Stability Evaluation	Pass On Going Stability Evaluation

The test results indicate that the proposed Verify V24 Self-Contained Biological Indicator is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2009

Mr. John Robert (Jack) Scoville, Jr
Fellow, Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

Re: K090514
Trade/Device Name: Verify® V24 Self-Contained Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: February 25, 2009
Received: February 26, 2009

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting 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): **K090514**

Device Name: Verify® V24 Self-Contained Biological Indicator

Indications For Use:

The Verify® V24 Self-Contained Biological Indicator is intended as a standard method for frequent monitoring of the Amsco® V-PRO™ 1 Low Temperature Sterilization System.

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)

Shirley N Murphy MD

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

510(k) Number: K090514