OCT 2 0 2005

510(k) Summary
for
Verify® Self-Contained Biological Indicator

1. SPONSOR

Albert Browne Ltd., subsidiary of STERIS Corporation
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

Contact: Richard Bancroft
Telephone: 0116 276 8636

Date Prepared: October 5, 2005

2. DEVICE NAME

Proprietary Name:	Verify® Self-Contained Biological Indicator
Common/Usual Name:	Biological indicator
Classification Name:	Biological sterilization process indicators

3. PREDICATE DEVICE

- Verify® Self-Contained Biological Indicator (cleared as the Assert™ Biological/Chemical Indicator, K855101)

4. DEVICE DESCRIPTION

The proposed Verify® Self-Contained Biological Indicator (SCBI) is identical in components, design, materials, and manufacturing specifications to the predicate Verify® Self-Contained Biological Indicator (cleared in K855101 as the Assert™ Biological/Chemical Indicator). The SCBI consists of a plastic vial that contains a disc inoculated with *Geobacillus stearothermophilus* and/or *Bacillus atrophaeus* spores and an ampoule of culture media.

The predicate device was cleared for use in 250°F (121°C) gravity steam, 270°F (132°C) gravity flash steam, 270°F (132°C) prevacuum steam, and ethylene oxide sterilization cycles. This 510(k) premarket notification was submitted to expand the indications for use for the biological indicator to include the Express abbreviated prevacuum steam sterilization cycle (see Section 5).

5. INTENDED USE

The Verify® Self-Contained Biological Indicator described in this 510(k) premarket notification may be used for installation testing and routine monitoring of the following steam sterilization cycle:

- 270°F (132°C), 4 min. Express abbreviated prevacuum steam sterilization cycle for packaged items

6. PERFORMANCE TESTING

Performance testing was conducted to validate the SCBI for use in the Express abbreviated prevacuum steam sterilization cycle. The results support the use of the SCBI for monitoring this cycle and confirms that the SCBI meets the current requirements of FDA guidance and relevant industry standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 2 0 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Albert Brown Limited
C/O Cynthia J. M. Nolte, Ph.D., RAC
Senior Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K051056
Trade/Device Name: VERIFY SELF-CONTAINED BIOLOGICAL INDICATOR
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: October 5, 2005
Received: October 6, 2005

Dear Dr. Nolte:

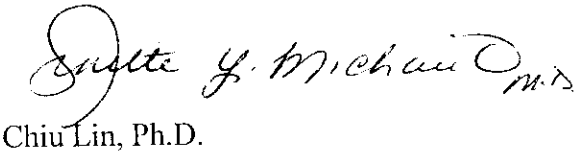
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.
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): K051056

Device Name: Verify® Self-Contained Biological Indicator

Indications for Use:

The Verify® Self-Contained Biological Indicator may be used for installation testing and routine monitoring of the following steam sterilization cycle:

- 270°F (132°C), 4 min. Express abbreviated prevacuum steam sterilization cycle for packaged items

Prescription Use _____ AND/OR Over-The-Counter Use __x__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/19/05

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

510(k) Number: K051056