DEC 6 2005

510(k) Summary
for
Verify Flash Integrator

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: December 1, 2005

2. DEVICE NAME

Proprietary Name:	Verify Flash Integrator
Common/Usual Name:	Chemical indicator
Classification Name:	Physical/chemical sterilization process indicator

3. PREDICATE DEVICE

- TST Control Integrator for Steam Sterilizers (K002937)

4. DEVICE DESCRIPTION

The proposed Verify Flash Integrator is a polypropylene strip with two 12 mm circular chemical indicator ink spots, one located on either side of a reference circle exhibiting the endpoint color. The stated values for the two indicator inks printed on the Verify Flash integrator are provided in Table 1.

Table 1. Stated Values for Verify Flash Integrator Inks

Temp (°C/°F)	Exposure Time (Min.)
132/270	10
132/270	4

5. INTENDED USE

The Verify Flash Integrator is an integrating integrator that changes color from yellow to blue/purple when exposed to the following conditions:

- 270°F (132°C), 10 min. flash gravity steam sterilization
- 270°F (132°C), 4 min. Express abbreviated prevacuum steam sterilization

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Verify Flash Integrator and the predicate TST Control Integrator indicate exposure to critical combination(s) of temperature and exposure time through a visible color change in an indicator ink spot printed on polypropylene. Differences between the proposed and predicate integrators are limited to minor differences in the materials used for construction of the strip and the indicator ink composition.

7. PERFORMANCE TESTING

Data was provided that demonstrates that the Verify Flash Integrator meets the requirements for Class 5 integrating indicators as defined in clauses 9.1 and 9.3 of ANSI/AAMI ST60-1996 "Sterilization of health care products – Chemical indicators – Part 1: General Requirements" for 132°C sterilization cycles. Simulated use testing confirms that the Verify Flash Integrator performed as expected in a 10 min. gravity flash and the 4 min. Express abbreviated prevacuum steam sterilization cycles at 132°C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 6 2005

Albert Browne Limited
C/O Dr. Cynthia J. M. Nolte
Senior Staff Consultant
Medical Device Consultant, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760-4153

Re: K051101
Trade/Device Name: Verify Flash Integrator
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: November 22, 2005
Received: November 23, 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.

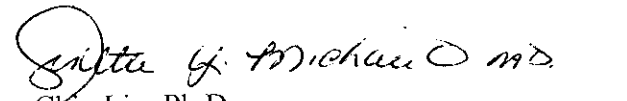
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number: K051101

Device Name: Verify Flash Integrator

Indications For Use:

The Verify Flash Integrator is an integrating integrator that changes color from yellow to blue/purple when exposed to the following conditions:

- 270°F (132°C), 10 min. flash gravity steam sterilization
- 270°F (132°C), 4 min. Express abbreviated prevacuum steam sterilization

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 NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

12/6/05

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K051101