15.0 Premarket Notification Summary

General Information

Sponsor

3M Company
3M Medical Division
3M Center
Building 275-5W-06
St. Paul, MN 55144-1000

Contact

Cynthia Lamarucciola
Phone: 651-736-1523
Fax: 651-737-5320
Email: cllamarucciola@mmm.com

Prepared February 20, 2003

Device Name

Common or Usual Name: Biological Indicator

Proprietary Name: 3M™ Attest™ 1294 Rapid Readout Biological Indicator for EO and 3M™ Attest™ 1298 Rapid Readout Biological Indicator for EO Test Pack

Classification Name: Biological Sterilization Process Indicators (21CFR§880.2800).

Establishment Registration Number

The establishment registration number for 3M Company is 2110898.

The 3M™Attest™ 1294 Rapid Readout Biological Indicator for EO is manufactured and packaged at the following facility:

3M Brookings
601 22nd Avenue
Brookings, SD 57006

Phone: 605-692-9433

FAX: 605-696-1397
Establishment Number 1717046

The 3M™Attest™ 1298 Rapid Readout Biological Indicator for EO Test Pack is assembled and packaged at the following facility:

3M Flemington
500 Route 202 North
Flemington, NJ 08822

Phone: 908-788-4000
FAX: 908-788-4101
Establishment Number 2222706

The 3M™ Attest™ 290G Auto-reader is manufactured and packaged at the following facility:

3M Company
1617 North Front Street
New Ulm, MN 56073

Phone: 651-733-7605
Fax: 651-737-5320
Establishment Number 2183581

The through-put chemical indicator utilized on the label of the 3M™ 1294 Rapid Readout Biological Indicator for EO and the 3M™Attest™ 1298 Rapid Readout Biological Indicator for EO Test Pack is manufactured and released by:

Propper Manufacturing Company, Inc.
36-04 Skillman Avenue
Long Island, NY 11101
Establishment Number 2410251

Device Classification

Class:	Class II
Classification Panel:	General Hospital (80)
Product Code:	FRC

Performance Standards

The FDA has developed no performance standards under Section 514 for biological indicators, reader/incubators or test packs. However, the following consensus standards and FDA draft guidance document were utilized to develop the test protocols outlined for the 3M™ Attest™ 1294 EO Rapid Readout Biological Indicator and the associated 3M™ Attest™ 1298 Test Pack, when used in conjunction with the 3M™ Attest™ Model 290G Auto-reader:

- ANSI/AAMI ST21:1986 Sterilization of Health Care Products-Biological Indicators-Part 2: Biological Indicators for Ethylene Oxide Sterilization (reaffirmed 1994)
- ANSI/AAMI ST21:1999 Sterilization of Health Care Products-Biological Indicators-Part 2: Biological Indicators for Ethylene Oxide Sterilization
- ANSI/AAMI ST41:1999 Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance
- ANSI/AAMI ST44:1992 BIER/EO Gas Vessels
- ANSI/AAMI ST59:1999 Sterilization of Health Care Products-Biological Indicators-Part 1: General
- United States Pharmacopoeia (USP) 25, General Notices; Storage Temperature and Monograph 1151, Stability, 2002
- Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers (Draft dated May 21, 2001)
- The Center for Devices and Radiological Health, FDA Guidance for Validation of Biological Indicator Incubation Time

Indication for Use

The 3M™ Attest™ 1294 Rapid Readout Biological Indicator for EO is used to monitor ethylene oxide sterilization cycles when used in conjunction with the 3M™ Attest™ 290G Auto-reader.

The 3M™ Attest™ 1298 Rapid Readout Biological Indicator for EO Test Pack is used to monitor ethylene oxide sterilization cycles when used in conjunction with the 3M™ Attest™ 290G Auto-reader.

The 3M™ Attest™ 290G Auto-reader is designed to incubate and automatically read the 3M™ Attest™ 1294 Rapid Readout Biological Indicators (RRBI) for EO at 37°C for a final negative fluorescence reading at 4 hours.

Device Description

The 3M™ Attest™ 1294 Rapid Readout Biological Indicator (RRBI) for EO (green cap) is a self contained device consisting of a standardized, viable population of *Bacillus atrophaeus*, (formerly *Bacillus subtilis*), spores specifically designed for the rapid, reliable monitoring of ethylene oxide (EO) sterilization processes when used in conjunction with the 3M™ Attest™ 290G Auto-reader.

The Attest 1294 RRBI for EO detects sterilization process failure through the activity of a naturally occurring enzyme, beta-glucosidase, produced by the organism during the germination and outgrowth process. The auto-reader detects the activity of this enzyme by reading a fluorescent product produced by the enzymatic breakdown of a substrate in the media. Presence of this enzyme indicates a sterilization process failure. The final negative biological indicator result, indicating an acceptable sterilization process, is made after 4 hours of incubation.

The Attest 1294 RRBI for EO may also be incubated for 7 days to obtain a visual pH color change. (The 7-day incubation is not intended for routine use and may be used to validate of the fluorescent results.) The biochemical activity of viable *Bacillus atrophaeus* produces acid by-products that cause the media to change from green to yellow. This visual pH color change also indicates a sterilization process failure however, due to the high sensitivity of the 4-hour fluorescent results, there is no advantage to incubate the Attest 1294 RRBI beyond 4 hours.

The 3M™ Attest™ 1298 Rapid Readout Biological Indicator (RRBI) for EO Test Pack is specifically designed to routinely challenge the ethylene oxide (EO) sterilization process when used in conjunction with the 3M™ Attest™ Model 290G Auto-reader.

This Test Pack is designed to present a challenge to the EO sterilization process comparable to the routine EO biological indicator pack recommended by ANSI/AAMI ST41 (1999).

Substantial Equivalence

The 3M™ Attest™ 1294 Rapid Readout Biological Indicator for EO uses the identical *Bacillus atrophaeus* (formerly *Bacillus subtilis* var. *niger*) spore species (ATCC 9372) as the Steris® Verify™, and produces the identical fluorescent byproduct as the 3M™ Attest™ 1292 Rapid Readout Biological Indicator (for steam).

The 3M™ Attest™ 1298 Rapid Readout Biological Indicator for EO Test Pack functions in the same manner as the ANSI/AAMI routine test pack for EO.

Description of Testing

Multiple lots of the Attest 1294 RRBI for EO were tested, and demonstrated performance, for: Resistance Characteristics, Spore Population and species confirmation, Media Recovery and 4-hour Fluorescent Readout Reliability.

Multiple lots of the Attest 1298 RRBI for EO Test Packs were tested for performance comparison to a routine test pack recommended by ANSI/AAMI ST 41.

Testing demonstrated that the Attest 1294 RRBI for EO is substantially equivalent to the named predicates, the Steris® Verify™ and the 3M™ Attest™ 1292 Rapid Readout Biological Indicator for Steam.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2003

3M Company
C/O Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K031012
Trade/Device Name: 3M™ Attest™ 1294 Rapid Readout Biological Indicator for EO, Model 1294
Regulation Number: 880.2800 (a)
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: October 10, 2003
Received: October 14, 2003

Dear Mr. Mosenkis:

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.

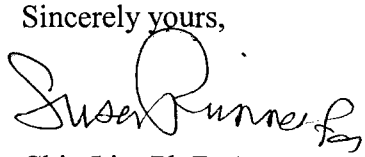
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/dsma/dsmamain.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

11.0 Indications for Use

510(k) Number (if known): K031012

Device Name: 3M™Attest™ 1294 Rapid Readout Biological Indicator for EO

Indications for Use:

The 3M™ Attest™ 1294 Rapid Readout Biological Indicator for EO is used to monitor ethylene oxide sterilization cycles when used in conjunction with the 3M™ Attest™ 290G Auto-reader.

The 3M™ Attest™ 1298 Rapid Readout Biological Indicator for EO Test Pack is a routine challenge pack used to monitor ethylene oxide sterilization cycles when used in conjunction with the 3M™ Attest™ 290G Auto-reader.

The 3M™ Attest™ 290G Auto-reader is designed to incubate and automatically read the 3M™ Attest™ 1294 Rapid Readout Biological Indicators (RRBI) for EO at 37°C for a final negative fluorescence reading at 4 hours.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter-Use ___

Patricia A.Y, Interim Branch Chief 10/16/03

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

510(k) Number K031012