K121484

Premarket Notification 510(k) Summary

OCT 19 2012

3M

Sponsor Information:

3M Health Care

3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person:	Suzanne Leung, Ph.D., RAC Regulatory Affairs
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Date of Summary:	October 4, 2012

Device Name and Classification:

Common or Usual Name:	Sterilization Biological Indicator
Proprietary Name:	3M Attest™ 1492V Super Rapid Readout Biological Indicator for Steam 3M Attest™ 490 Auto-reader
Classification Name:	Indicator, Biological Sterilization Process (21 CFR § 880.2800(a))

Predicate Devices:

- 'Intended Use Predicate' for 1492V - 3M Attest™ 1292 Rapid Readout Biological Indicator for Steam, K090569, K926364
- 'Design Predicate' for 1492V - 3M Attest™ 1491 Super Rapid Readout Biological Indicator for Steam, K103277
- 3M Attest™ 490 Auto-reader, K103277

Description of Device:

1492V

The 3M Attest™ 1492V Super Rapid Readout Biological Indicator (SRBI) is a self-contained biological indicator designed to be used with the 3M Attest™ 490 Auto-reader to qualify or routinely challenge dynamic-air-removal (prevacuum) steam sterilization cycles at 270°F (132°C) and at 275°F (135°C).

The Attest™ 1492V SRBI is composed of a polycarbonate sleeve containing a spore carrier and media ampoule, enclosed with a color-coded cap. On each 1492V SRBI cap is a chemical process indicator that changes color from pink to light brown when exposed to steam.

The 1492V SRBI is a further improvement over the current 3M Attest™ Rapid Readout technology. Both the Attest™ Rapid Readout BIs and the Attest™ Super Rapid Readout BIs utilize the α-glucosidase enzyme system, which is generated naturally within growing *G. stearothermophilus* organisms. The α-glucosidase enzyme in its active state is detected by measuring the fluorescence produced by the enzymatic hydrolysis of a non-fluorescent substrate. The resultant fluorescent by-product is detected in the 3M Attest™ 490 Auto-reader. The detection of fluorescence upon incubation of the 1492V SRBI in the 490 Auto-reader indicates a steam sterilization failure.

The 1492V SRBI is similar in design to the 3M Attest™ 1491 Super Rapid Readout Biological Indicator for Steam cleared as K103277 for gravity displacement steam sterilization cycles. Minor modifications were made to 1491 that resulted in the 1492V SRBI for dynamic-air-removal (prevacuum) steam sterilization cycles.

490 Auto-reader

The Attest™ 490 Auto-reader has been cleared for use with the Attest™ 1491 Super Rapid Readout Biological Indicator for Steam under K103277. The current submission extends the use of the 490 Auto-reader to the 1492V SRBI.

The Attest™ 490 Auto-reader is designed to incubate at 56°C and automatically read the Attest™ 1492V SRBI for a fluorescent result within 1 hour. The 490 Auto-reader is also designed to allow further incubation of the 1492V SRBI for an optional visual pH color change of the growth media at 48 hours. Both the fluorescent readout at 1 hour and the optional visual readout at 48 hours met the FDA's requirement of > 97% alignment with the result after the conventional incubation time of 7 days.

Indications for Use:

Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction with the 3M™ Attest™ Auto-reader 490 to qualify or monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles of 4 minutes at 270°F (132°C) and 3 minutes at 275°F (135°C).

The 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Testing was conducted on the biological indicator following the FDA guidance and standards below:

- FDA's *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions;* October 4, 2007
- ANSI/AAMI/ISO 11138-1:2006/(R)2010 *Sterilization of health care products – Biological indicators – Part 1: General Requirements*
- ANSI/AAMI/ISO 11138-3:2006/(R)2010 *Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes*
- ANSI/AAMI/ISO 18472:2006 *Sterilization of Health Care Product-Biological and Chemical Indicators: Test Equipment*
- United States Pharmacopeia, Chapter <1035> *Biological Indicators for Sterilization* and Chapter <55> *Biological Indicators – Resistance Performance Tests.*

Multiple lots of 3M Attest™ 1492V SRBIs were evaluated for performance when used with the 3M Attest™ 490 Auto-reader. A Summary of the Nonclinical Testing is shown on the following page.

Summary of Nonclinical Testing

Biological Indicator Test	Acceptance Criteria	Result
Characterization of spores	> 90% Genetic similarity to *Geobacillus stearothermophilus* ATCC™ 7953	Pass
D-Value	Greater than or equal to 10 seconds at 132°C Greater than or equal to 8 seconds at 135°C	Pass
Population (Total Viable Spore Count)	Greater than or equal to 10^6 spores	Pass
Survival/Kill Times	Survival Time = Calculated survival time* or 1 minute at 132°C and 40 seconds at 135°C, whichever is longer; Kill time = Calculated kill time* at 132°C and at 135°C *ANSI/AAMI/ISO 11138-1:2006/(R) 2010, Annex E	Pass
Reduced Incubation Time	Meets FDA's requirements for Reduced Incubation Time with > 97% alignment with the conventional incubation time of 7 days for the following readout times: • Fluorescent result in 1 hour • Optional visual pH color change at 48 hours	Pass
Hold Time Assessment	D-value does not change when activated 7 days post-sterilization	Pass
Component Inhibition Studies	Components have no impact on the recovery of 10-100 organisms	Pass
Chemical Process Indicator	Chemical Process Indicator on the BI changes from pink to light brown upon exposure to steam	Pass
Auto-reader Maintenance of Incubation Temperature	Maintain 56+/- 2°C over a period of 7 days	Pass

The results of these evaluations showed that the new Attest™ 1492V Rapid Readout Biological Indicator, when used with the Attest™ 490 Auto-reader, complies with ANSI/AAMI/ISO 11138-1:2006/(R)2010 and ANSI/AAMI/ISO 11138-3:2006/(R)2010, the USP requirements for biological indicators, as well as the FDA's Guidance for Biological Indicators.

The Attest™ 490 Auto-reader was tested for safety by Underwriters Laboratory to verify compliance to:

- *IEC 61010-1 (2001) Second Edition; Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements,*
- *IEC 61010-2-010 (2003) Second Edition; Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials, and*
- *IEC 60825-1 (1993) First Edition with Am. 1(1997) and Am. 2 (2001); Standard for safety of laser products – Part 1: Equipment classification and requirements.*

In addition, the Attest™ 490 Auto-reader has been tested by a certified Testing Laboratory to verify electromagnetic compatibility per:

- USA Title 47, Code of Federal Regulations (2009) for:
  - Radiated Emissions (FCC Part 15, Subpart B, Class A)
  - Conducted Emissions (FCC Part 15, Subpart B, Class A), and
- IEC 61326: *Electrical Equipment for Measurement, Control and Laboratory Use—EMC Requirements.*

Conclusion

The 3M Attest™ 1492V Super Rapid Readout Biological Indicator and the 3M Attest™ 490 Auto-reader meet all applicable performance standards and are substantially equivalent to their predicate devices in terms of their intended use, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

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

OCT 19 2012

3M Health Care
C/O Suzanne Leung, Ph.D., RAC
Regulatory Affairs
3M Center Bldg. 275-5W-06
St. Paul, Minnesota 55144

Re: K121484
Trade/Device Name: 3M Attest™ 1492V Super Rapid Readout Biological Indicator for Steam, 3M Attest™ 490 Auto Reader
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: October 17, 2012
Received: October 18, 2012

Dear Ms. Leung:

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,

for

Anthony D. 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

510(k) Number: K121484

Device Name: 3M Attest™ 1492V Super Rapid Readout Biological Indicator for Steam
3M Attest™ 490 Auto-reader

Indications for Use:

Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction with the 3M™ Attest™ Auto-reader 490 to qualify or monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles of 4 minutes at 270°F (132°C) and 3 minutes at 275°F (135°C).

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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)

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

510(k) Number: K121484