DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 21, 2017

3M Company
C/O Hilary Hovde
Regulatory Affairs Associate
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144

Re: K171003
Trade/Device Name: 3M Attest Rapid Readout Biological Indicator 1295, 3M Attest Auto-reader 490H
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: June 29, 2017
Received: June 30, 2017

Dear Hilary Hovde:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tara A. Ryan -S

for
Lori Wiggins
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171003

Device Name
3M™ Attest™ Rapid Readout Biological Indicator 1295 and 3M™ Attest™ Auto-reader 490H

Indications for Use *(Describe)*
Use the 3M™ Attest™ Rapid Readout Biological Indicator in conjunction with the 3M™ Attest™ Auto reader 490H as a standard method of routine monitoring of vaporized hydrogen peroxide sterilization processes in the Amsco® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), and in STERRAD® 100S, STERRAD® NX® (Standard and Advanced cycles) and STERRAD® 100NX® (Standard, Flex, Express, and Duo cycles) systems.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
for
3M™ Attest™ Rapid Readout Biological Indicator 1295 and 3M™ Attest™ Auto-reader 490H

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

Contact: Hilary B. Hovde
Regulatory Affairs Associate
Phone Number: (651) 736-0364
FAX Number: (651) 737-5320

Submission Date: July 20, 2017

K171003

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Attest™ Rapid Readout Biological Indicator 1295 and 3M™ Attest™ Auto-reader 490H

Device Name and Classification:

Common or Usual Name:	Biological Indicator
Proprietary Name:	3M™ Attest™ Rapid Readout Biological Indicator 1295 3M™ Attest™ Auto-Reader 490H
Classification Name:	Indicator, Biological Sterilization Process (21 CFR § 880.2800(a))
Device Classification:	Class II
Product Code:	FRC

Predicate Device:

- Intended use Predicate for system – K160546 - 3M™ Attest™ Rapid Readout Biological Indicator 1295
- 3M™ Attest™ Auto-reader 490H, K140392

Description of Device:

The 3M™ Attest™ Rapid Readout Biological Indicator 1295 is a self-contained biological indicator specifically designed for rapid and reliable routine monitoring of vaporized hydrogen peroxide sterilization processes when used in conjunction with the 3M™ Attest™ Auto-reader 490H. The 1295 BI is a single-use device composed of a polycarbonate sleeve containing a spore carrier and media ampoule, enclosed with a color-coded cap. A chemical process indicator printed with stripes which change from blue toward pink upon exposure to vaporized hydrogen peroxide is located on the top of the cap. The detection of fluorescence upon incubation of the 1295 BI in the 490H Auto-reader indicates a sterilization failure.

Nonclinical Comparison to the Predicate Device

This submission is addressing a software change to the 3M™ Attest™ Auto-reader 490H to reduce the final fluorescent readout from 4 hours to 24 minutes. The 3M™ Attest™ Rapid Readout Biological Indicator 1295 is the same design as the previously cleared device of the same model number. The device has the same materials and fundamental scientific technology. The only change to the performance specifications is the change in final fluorescent readout from 4 hours to 24 minutes.

Summary of Nonclinical Testing

The effectiveness of the 3M™ Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M™ Attest™ Auto-reader 490H with a final fluorescent readout of 24 minutes is demonstrated in the following tests:

Test	Results
Positive Control	Passed
Survival Time = 5 seconds Kill Time = 7 minutes	Passed
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 time: • 24 minutes	Passed

Summary of Clinical Testing

No clinical data was included in this premarket application submission.

Indications for Use

Use the 3M™ Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring of vaporized hydrogen peroxide sterilization processes in the AMSCO® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), and in STERRAD® 100S, STERRAD® NX® (Standard and Advanced cycles) and STERRAD® 100NX® (Standard, Flex, Express and Duo cycles) systems.

Comparison to Predicate Device

Feature	Submission Device: 3M™ Attest™ Rapid Readout Biological Indicator 1295 and 3M™ Attest™ Auto-reader 490H	Predicate Device (K160546): 3M™ Attest™ Rapid Readout Biological Indicator 1295 and 3M™ Attest™ Auto-reader 490H
Indications for use	Use the 3M™ Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring of vaporized hydrogen peroxide sterilization processes in the Amsco® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), and in STERRAD® 100S, STERRAD® NX® (Standard and Advanced cycles) and STERRAD® 100NX® (Standard, Flex, Express and Duo cycles) systems.	Identical
Organism	*Geobacillus stearothermophilus* traceable to ATCC™ 7953	Identical
Viable spore population	$\geq 1 \times 10^6$	Identical
Resistance characteristics • D-value • Survival/Kill Window	(Tested at 10 mg/L vaporized hydrogen peroxide) $D_{10\ mg/L} \geq 1$ second Survival Time ≥ 5 seconds Kill Time = 7 minutes	Identical
Carrier material	polyethylene terephthalate	Identical
Incubation temperature	60 ± 2^oC	Identical
Readout time	24 minute fluorescence result read in the 3M™ Attest™ Auto-reader 490H	4 hour fluorescence result read in the 3M™ Attest™ Auto-reader 490H
Chemical indicator	H2O2 sensitive ink; changes from blue towards pink	Identical
Shelf-life	24 months	Identical

Conclusion

The 3M™ Attest™ Rapid Readout Biological Indicator 1295 and the 3M™ Attest™ Auto-reader 490H meet all applicable standards and are substantially equivalent to their predicate devices in terms of their intended use, physical properties and technological characteristics.