



Food and Drug Administration
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June 9, 2016

3M Health Care
Ms. Hilary B. Hovde
3M Health Care Regulatory Affairs Specialist
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144

Re: K160546

Trade/Device Name: 3M™ Attest™ Rapid Readout Biological Indicator 1295
Regulation Number: 21 CFR 880.2800
Regulation Name: Indicator, Biological Sterilization Process
Regulatory Class: Class II
Product Code: FRC
Dated: May 12, 2016
Received: May 17, 2016

Dear Hilary B. 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" (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 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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160546

Device Name

3M™ Attest™ Rapid Readout Biological Indicator 1295

Indications for Use (Describe)

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 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Premarket Notification (510(k)) Summary

K160546



Sponsor Information:

3M Health Care
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St. Paul, MN 55144-1000

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

Date of Summary: June 7, 2016

Device Name and Classification:

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

Predicate Devices:

- K152060 - 3M™ Attest™ Rapid Readout Biological Indicator 1295

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 to pink upon exposure to vaporized hydrogen peroxide is located on the top of the cap. The 1295 BI utilizes the same fundamental technology that exists in current 3M™ Attest™ Rapid Readout and Super Rapid Readout BIs. 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 clearance for use in an additional sterilizer. 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, performance specifications, and fundamental scientific technology.

Summary of Nonclinical Testing

The effectiveness of the 3M™ Attest™ Rapid Readout Biological Indicator 1295 in the Amsco® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles) is demonstrated in the following tests:

Test	Results
Verification of performance in full cycles in the Amsco® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles)	Passed
Growth promotion ability in the Amsco® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles)	Passed
Verification of half cycles in the Amsco® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles)	Passed
Verification of performance in fractional cycles in the Amsco® V-PRO® maX Low Temperature Sterilization System	Passed
Verification of 4-hour fluorescent readout per FDA's Reduced Incubation Time protocol in the Amsco® V-PRO® maX Low Temperature Sterilization System	Passed
Verification of population and resistance characteristics (D-value, survival, kill) at the end of shelf life in the Amsco® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles)	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 100NX (Standard, Flex, Express and Duo cycles) systems.

Comparison to Predicate Device

Feature	Submission Device: 3M™ Attest™ 1295 Biological Indicator	Predicate Device (K152060): 3M™ Attest™ 1295 Biological Indicator
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 100NX (Standard, Flex, Express and Duo cycles) systems.	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 STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles) and 100NX (Standard, Flex, Express and Duo cycles) systems.
Organism	<i>Geobacillus stearothermophilus</i> traceable to ATCC™ 7953	Same
Viable spore population	$\geq 1 \times 10^6$	Same
Resistance characteristics <ul style="list-style-type: none"> D-value Survival/Kill Window 	(Tested at 10 mg/L vaporized hydrogen peroxide) $D_{10 \text{ mg/L}} \geq 1 \text{ second}$ Survival Time $\geq 5 \text{ seconds}$ Kill Time = 7 minutes	Same
Carrier material	Polyethylene terephthalate	Same
Incubation temperature	60 +/- 2 °C	Same
Readout time	4 hour fluorescence result read on 3M 490H Auto-reader	Same
Chemical indicator	H2O2 sensitive ink; appears blue until processed, then appears pink	Same
Shelf-life	18 months	Same

Conclusion

The 3M™ Attest™ Rapid Readout Biological Indicator 1295 is substantially equivalent to the predicate device in terms of their intended use, physical properties and technological characteristics. The non-clinical testing demonstrates that the 1295 Biological Indicator is as safe, as effective, and performs as well as the predicate device.