DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 9, 2018

3M Health Care
Ms. Nadia Battah
Regulatory Affairs Associate
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Re: K173435

Trade/Device Name: 3M™ Attest™ Rapid Readout Biological Indicator 1295
Regulation Number: 21 CFR 880.2800
Regulation Name: Biological Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: January 05, 2018
Received: January 08, 2018

Dear Ms. Nadia Battah:

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 yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173435

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 following systems: AMSCO® V-PRO™ 1 Low Temperature Sterilization System (Lumen cycle), AMSCO® V-PRO™ 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles), AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), AMSCO® V-PRO™ 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) and in STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles), STERRAD® 100NX (Standard, Flex, Express and Duo cycles) systems, STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles) and STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express and Duo cycles).

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

Sponsor Information:

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

Contact: Nadia Battah
Regulatory Affairs Associate
Phone Number: (651) 733-0929
Fax Number: (651) 737-5320

Date of Summary: February 6, 2018

Submission Number: K173435

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Attest™ Rapid Readout Biological Indicator 1295

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 Device:

- K171003 - 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 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.

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 following systems: AMSCO® V-PRO™ 1 Low Temperature Sterilization System (Lumen cycle), AMSCO® V-PRO™ 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles), AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), AMSCO® V-PRO™ 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) and in STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles), STERRAD® 100NX (Standard, Flex, Express and Duo cycles) systems, STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles) and STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express and Duo cycles).

Nonclinical Comparison to the Predicate Device

The 3M™ Attest™ Rapid Readout Biological Indicator 1295 is the same design as the previously cleared device of the same model number (the predicate) which is sold under the tradename 3M™ Attest™ Rapid Readout Biological Indicator 1295 (K171003).

There has been no change to the device's design, materials, physical/chemical characteristics, performance specifications or fundamental scientific technology or to the device's accessory, the 3M Attest™ Auto-reader 490H. The intent of this submission is to expand the indications for use to include use in additional sterilizers.

Summary of Nonclinical Testing

Nonclinical testing of the 3M™ Attest™ Rapid Readout Biological Indicator 1295 was conducted in accordance with the *FDA Guidance for Industry and FDA Staff: Biological Indicator (BI) Premarket Notification [510(k)] Submissions*, and ANSI/AAMI/ISO 11138-1:2006/(R) 2010 Sterilization of health care products- Biological indicators- Part 1: General requirements (FDA Recognition Number 14-296).

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:

Performance Test	**Results**
Full Cycle Performance Verification – STERRAD® NX with ALLClear™ Technology, STERRAD® 100NX with ALLClear™ Technology, AMSCO® V-PRO™ 1, AMSCO® V-PRO™ 1 Plus and AMSCO® V-PRO 60	Pass
Half Cycle Performance Verification – STERRAD® NX with ALLClear™ Technology, STERRAD® 100NX with ALLClear™ Technology, AMSCO® V-PRO™ 1, AMSCO® V-PRO™ 1 Plus and AMSCO® V-PRO 60	Pass
Chemical Indicator (CI) Color Change	Pass
Verification of population characteristics	Pass

Summary of Clinical Testing

No clinical data was included in this premarket application submission.

Comparison to Predicate Device

Feature	Submission Device: 3M™ Attest™ Rapid Readout Biological Indicator 1295	Predicate Device (K171003): 3M™ Attest™ Rapid Readout Biological Indicator 1295
Device Models	1295	Identical.
Intended Use	Monitoring of vaporized hydrogen peroxide sterilization processes.	Identical.
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 following systems: AMSCO® V-PRO™ 1 Low Temperature Sterilization System (Lumen cycle), AMSCO® V-PRO™ 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles), AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), AMSCO® V-PRO™ 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) and in STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles), STERRAD® 100NX (Standard, Flex, Express and Duo cycles) systems, STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles) and STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express and Duo cycles).	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.
Device Design	The 3M Attest™ 1295 Rapid Readout Biological Indicator (1295 BI) is a self-contained biological indicator that contains greater than $1x10^6$ *Geobacillus stearothermophilus* spores on a carrier within the device. During activation, the cap is depressed fully onto the sleeve which pushes the growth media ampoule into the ampoule crusher, causing the glass ampoule to break and allowing the liquid growth media to flow down to the spores. After activation, the cap has a surface that seals against the sleeve which closes the sterilant entry ports and contains the liquid growth media within the BI.	Identical.

Organism	*Geobacillus stearothermophilus* traceable to ATCC™ 7953	Identical.
Viable spore population	$\geq 1x10^6$	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	Identical.
Chemical indicator	H_2O_2 sensitive ink; changes from blue towards pink	Identical.
Shelf-life	24 months.	Identical.

Conclusion

The results of the studies demonstrate that the biological indicator performs as intended, and based on the nonclinical tests performed, the subject device is substantially equivalent to, and is as safe and as effective as the legally marketed predicate device, K171003, Class II (21 CFR 880.2800, Product code FRC).