May 21, 2024

3M Company
Michelle Larsen
Advanced Regulatory Affairs Specialist
3M Center
2510 Conway Ave., Building 275-5W-06
St. Paul, Minnesota 55144

Re: DEN230068
Trade/Device Name: 3M™ Attest™ eBowie-Dick Test Card 10135 3M™ Attest™ eBowie-Dick Card Holder 10135CH 3M™ Attest™ eBowie-Dick Auto-reader 1190
Regulation Number: 21 CFR 880.2801
Regulation Name: Digital physical/chemical sterilization process sensor
Regulatory Class: Class II
Product Code: SBE
Dated: September 27, 2023
Received: September 29, 2023

Dear Michelle Larsen:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the 3M™ Attest™ eBowie-Dick Test Card 10135, 3M™ Attest™ eBowie-Dick Card Holder 10135CH, 3M™ Attest™ eBowie-Dick Auto-reader 1190, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

3M™ Attest eBowie Dick Test Card and 3M™ Attest eBowie-Dick Card Holder

As a Sterilizer Monitoring Device, the 3M™ Attest™ eBowie-Dick Test Card 10135 and 3M™ Attest™ eBowie-Dick Card Holder 10135CH is used in conjunction with the 3M™ Attest™ eBowie-Dick Auto-reader 1190 to monitor the equipment performance of steam sterilizers each day, as well as after a steam sterilizer repair. The 3M™ Attest™ eBowie-Dick Test Card 10135 will detect steam penetration as a means of measuring air removal efficiency. The 3M™ Attest™ eBowie-Dick Test Card 10135 and 3M™ Attest™ eBowie-Dick Card Holder 10135CH is designed for testing air removal efficiency of 132°C (270°F), 134°C (273°F), and 135°C (275°F) for 3.5 minute test cycles in dynamic-air-removal steam sterilizers with chamber volumes greater than 54L (approximately 2 cubic feet).

3M™ Attest eBowie-Dick Auto-reader

The 3M™ Attest™ eBowie-Dick Auto-reader is designed to automatically interpret, store, and display the result of the 3M™ Attest™ eBowie-Dick Test Card.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the 3M™ Attest™ eBowie-Dick Test Card 10135 3M™ Attest™ eBowie-Dick Card Holder 10135CH 3M™ Attest™ eBowie-Dick Auto-reader 1190 and substantially equivalent devices of this generic type, into Class II under the generic name Digital physical/chemical sterilization process sensor.

FDA identifies this generic type of device as:

> **Digital physical/chemical sterilization process sensor**. A digital physical/chemical sterilization process sensor is a device intended to monitor one or more parameter(s) of the sterilization process. The adequacy of the sterilization conditions as measured by the parameter(s) is/are indicated by a digital readout of the result.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On September 29, 2023, FDA received your De Novo requesting classification of the 3M™ Attest™ eBowie-Dick Test Card 10135 3M™ Attest™ eBowie-Dick Card Holder 10135CH 3M™ Attest™ eBowie-Dick Auto-reader 1190. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the 3M™ Attest™ eBowie-Dick Test Card 10135 3M™ Attest™ eBowie-Dick Card Holder 10135CH 3M™ Attest™ eBowie-Dick Auto-reader 1190 into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the 3M™ Attest™ eBowie-Dick Test Card 10135 3M™ Attest™ eBowie-Dick Card Holder 10135CH 3M™ Attest™ eBowie-Dick Auto-reader 1190 can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Infection resulting from exposure to unsterile instruments due to false passing results or failure to properly monitor sterilizer performance	Non-clinical performance testing Software verification, validation, and hazard analysis
Delayed or cancelled procedure due to false positive results	Non-clinical performance testing Software verification, validation, and hazard analysis

Risks to Health	Mitigation Measures
Electrical shock	Electrical safety testing Non-clinical performance testing
Interference with other devices	Electromagnetic compatibility testing Electrical safety testing

In combination with the general controls of the FD&C Act, the digital physical/chemical sterilization process sensor is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must fulfill the following:
   (i) Testing must compare performance with a scientifically justified comparator;
   (ii) Testing must demonstrate that the measured response is dependent on the sterilization cycle parameter(s);
   (iii) Testing must identify relevant validation parameters (analytical performance characteristics) and include scientifically justified samples, conditions, and data analysis to evaluate said parameters with established acceptance criteria for each parameter;
   (iv) Testing must evaluate sensitivity and specificity to determine conditions for passing and failing results;
   (v) Testing must determine and validate accuracy, precision, and range of the measuring device;
   (vi) Testing must evaluate end point stability; and
   (vii) Testing must demonstrate that the reader maintains a defined range of accuracy over a defined time interval.

(2) Performance data must support the shelf life of the device by demonstrating continued device functionality over the labeled shelf life under the proposed storage conditions. Transport stability testing must demonstrate device resilience to transport conditions.

(3) Software verification, validation, and hazard analysis must be performed for any software components.

(4) Performance data must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Digital physical/chemical they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Claire Briglia at claire.briglia@fda.hhs.gov.

Sincerely,

Binita S. Ashar -S

Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical
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