DE NOVO CLASSIFICATION REQUEST FOR 3M™ ATTEST™ EBOWIE-DICK TEST

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 880.2801

CLASSIFICATION: Class II

PRODUCT CODE: SBE

BACKGROUND

DEVICE NAME: 3M™ Attest™ eBowie-Dick Test Card, 3M™ Attest™ eBowie-Dick Card Holder, 3M™ Attest™ eBowie-Dick Auto-reader

SUBMISSION NUMBER: DEN230068

DATE DE NOVO RECEIVED: September 29, 2023

SPONSOR INFORMATION:

3M Company
2510 Conway Ave.
St. Paul, MN 55144 USA

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.

LIMITATIONS

The 3M™ Attest™ eBowie-Dick Test is intended to be marketed for Over-The-Counter (OTC) use.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS

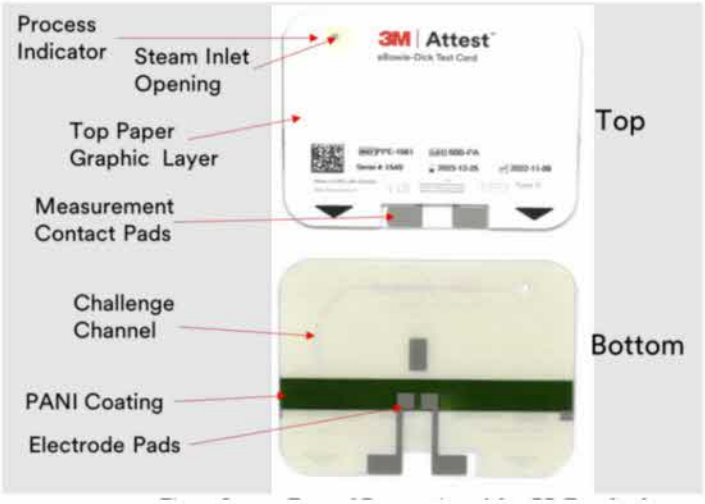
DEVICE DESCRIPTION

The 3M™ Attest™ eBowie-Dick Test Card consists of a laminated construction with a lead-free steam-sensitive chemical indicator positioned at the end of a lumen challenge. The 3M™ Attest™ eBowie-Dick Test Card undergoes a change in electrical resistance upon exposure to saturated steam. The test card includes a lumen challenge which is designed to restrict air removal and steam perfusion. At the completion of a Bowie-Dick test cycle, the resistance of the 3M™ Attest™ eBowie-Dick Test Card is read out using the 3M™ Attest™ eBowie-Dick Auto-reader. The 3M™ Attest™ eBowie-Dick Test Card will reach a PASS value when adequate air removal and steam profusion is achieved. An air removal failure and or a steam penetration failure is indicated by a FAIL result.

The 3M™ Attest™ eBowie-Dick Card Holder is a reusable sterilizable plastic container for the Test Card which serves to support the laminated construction of the Test Card during the vacuum and pressure cycles of the air removal test, as well as anchor the Test Card in place inside the sterilization chamber through the increased mass of the Card Holder plus Test Card combination.

The 3M™ Attest™ eBowie-Dick Auto-reader is a wall powered electrical resistance measurement device which receives a processed Test Card via the card slot and contains pairs of internal mechanical contacts to probe the metallic contact pads on the Test Card. The Auto-reader detects and confirms proper insertion of the Test Card, measures the PANI sensor electrical resistance, and returns a visible PASS, FAIL, or ERROR state indication to the user. The Auto-reader utilizes embedded firmware to detect and read the resistance of a Test Card. The device also includes USB or BLE connectivity for integrating with the optional 3M™ Attest™ Connect Software platform.


3M™ Attest™ Connect PC Application
eBowie-Dick Test Card
3M | Attest
Sign in to your account to download 3M™ Attest™ Connect software.
Sign in
eBowie-Dick Card Holder
eBowie-Dick Auto-reader
3M Attest


Process Indicator
Steam Inlet Opening
Top Paper Graphic Layer
Measurement Contact Pads
Challenge Channel
PANI Coating
Electrode Pads
Top
Bottom

SUMMARY OF BENCH STUDIES

REPROCESSING, STERILITY AND SHELF-LIFE

The 3M™ Attest™ eBowie-Dick Test Card is single use and does not require reprocessing or sterilization. A shelf-life study and a hot and cold excursion stability study are provided to demonstrate that the product performance (e.g., Fail Cycle, Pass Cycle, and Process Indicator Dot Color) is maintained throughout the 6-month shelf life of the device.

3M™ Attest™ eBowie-Dick Auto-reader do not require reprocessing or sterilization. Cleaning instructions for the 3M™ Attest™ eBowie-Dick Auto-reader are included in the labeling.

The 3M™ Attest™ eBowie-Dick Card Holder is a device that does not have a designated shelf life due to its ability to be replaced. A re-use study is provided to support the re-use of the Card Holder for up to 500 uses in steam sterilization. The Instructions for Use has information pertaining to the maintenance of the Card Holder.

BIOCOMPATIBILITY

The 3M™ Attest™ eBowie-Dick Test does not have any direct or indirect tissue contacting components.

SOFTWARE

The 3M™ Attest™ eBowie-Dick Auto-reader utilizes embedded firmware to detect and read the resistance of a 3M™ Attest™ eBowie-Dick Test Card. The embedded firmware stores measurements, which determine individual card results by comparing the measured resistance against a predefined threshold. Adequate software development, test plans, and documentation were demonstrated according to FDA guidance document, "Content of Premarket Submissions for Device Software Functions", Content of Premarket Submissions for Device Software Functions (fda.gov).

The hardware interfaces of the device provide users with access to the most recent 1000 records. They also allow remote firmware update. Additionally, they offer the ability to enable or disable an audible alarm and configure the date and time settings. These interfaces include:

1) CDC over USB connection.
2) (b)(4) Bluetooth (b)(4) Module.

The 3M™ Attest™ eBowie-Dick Auto-reader can be connected via USB and BLE connection to a Windows PC. This allows communications between the auto-reader and PC, where such communications are directed to a PC application that collects results and configuration. The name of the PC application is 3M™ Attest™ Connect. Attest Connect

can also facilitate firmware updates over the USB or BLE connection and enable or disable the audible alarm.

A backend server with a database, web services, and a registration portal developed and hosted in 3M's Azure Cloud infrastructure will be utilized as part of the Attest™ Connect app. This cloud server will be used to collect some customer information and data on cards read. It will also keep all the Auto-reader configurations from manufacturing and will be checked real time when card results are uploaded. With this check, 3M can monitor if any Attest™ Auto-reader configurations have changed. Additionally, the backend cloud server will facilitate application and firmware updates.

Adequate cybersecurity and software functionality were demonstrated according to FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

3M controls deployment of software updates as per change control and procedures within the Software Development Plan. All potential firmware and software updates are reviewed against the most recent versions of the SRS.

ELECTROMAGNETIC COMPATIBILITY & ELECTRICAL SAFETY

EMC Immunity testing was conducted on the Auto-reader using consensus standard 60601-1-2 and includes testing to IEC 61000-4-8 with levels directed by IEC 60601-1- 2. Electrical Safety testing was conducted per IEC 61010-1.

HUMAN FACTORS

The 3M™ Attest™ eBowie-Dick Test System was evaluated via simulated-use testing with users representative of the use specification in accordance with the guidance "Applying Human Factors and Usability Engineering to Medical Devices." This study included identification of known risks for commercially available similar devices, analysis of similarities and differences between potential use errors, risks, and harms, and evaluation of the risk mitigations and residual risks. No use errors, close calls or difficulties were observed during the use of the 3M™ Attest™ Electronic Bowie-Dick (eBD) System for Critical Task related Use Scenarios. In conclusion, the results demonstrate that the 3M™ Attest™ eBowie-Dick Test System, with the associated risk control measures, are safe and effective, and no design or labeling modifications are necessary.

PERFORMANCE TESTING – BENCH

The sponsor conducted the following performance tests to support that the device can achieve its intended use:

- Comparison of air pocket size and position in a reference test pack to the sensor size

and location in eBD Test card for an inadequate cycle to demonstrate comparable pass/fail testing performance to the test pack.
- Comparison of air pocket size and position in a reference test pack to the sensor size and location in eBD Test card to determine the impact of the presence of non-condensable gasses.
- Characterization of air removal from eBD Test card lumen construction and demonstration of equivalence to reference test pack.
- Testing of the sensor in the standard test pack in adequate and inadequate cycles to show expected pass/fail results.
- Quantifying the relationship between the resistance and the color of the sensor to show that they are related to the oxidation state of the polymer.
- Sensitivity and specificity testing as a function of changes in the vacuum level and pressure reached during the conditioning phase of a dynamic air removal cycle to support low occurrences of false positive and/or false negative results.
- Determination of equivalent performance to the Standard Test Pack as defined in ISO 11140:2007-5.
- Determination of accuracy, precision, and dynamic range of the 3M™ Attest™ eBowie-Dick Auto-reader 1190 for measuring resistance.
- Testing showing endpoint stability for Adequate and Inadequate Cycles as a function of Dwell Time in the sterilizer at the completion of a test cycle as well as a function of cooling time (referred to as Measurement Time in the report) once the device is removed from the sterilizer and before reading the test result.
- Independent verification of Auto-reader accuracy is completed during manufacturing final functional testing using external reference cards with verified resistance values.

LABELING

The labeling consists of a user manual, instructions for use, and packaging labels.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a digital, physical/chemical sterilization process indicator and the measures necessary to mitigate these risks.

Identified Risks to Health and Mitigation Measures

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
Electrical shock	Electrical safety testing Non-clinical performance testing

Risks to Health	Mitigation Measures
Interference with other devices	Electromagnetic compatibility testing Electrical safety testing

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

Risks:

The risks of the device are based on nonclinical laboratory testing described above.

The main probable risk of the proposed device is false results which may lead to ineffective sterilization of medical devices with a false negative result or may lead to re-running the Bowie-Dick cycle with a false positive result that causes a delayed procedure or procedures. There is an additional risk of electrical shock and interference with other devices. Both are mitigated with the performance testing, warnings, precautions, and special controls.

Benefits:

The probable benefits of the device are based on non-clinical laboratory testing described above.

The probable benefits of the subject device, include:

1) increases testing sensitivity with a digital measurement
2) reduces false results and repeat testing with an automatic reader
3) general patient benefit with improved sterilization process monitoring that reduces the risk of infection from improperly sterilized devices.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

Based on the performance testing provided (in particular; sensitivity, end point stability, shelf life, software validation, labeling, and human factors study), the sponsor has adequately supported that the subject device is a digital physical/chemical sterilization process sensor.

In conclusion, given the testing provided above, for the following indication statement:

> As a Sterilizer Monitoring Device, the 3M™ Attest™ eBowie-Dick Test Card and 3M™ Attest eBowie-Dick Card Holder are used in conjunction with the 3M™ Attest™ eBowie-Dick Auto-reader 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 will detect steam penetration as a means of measuring air removal efficiency. The 3M™ Attest™ eBowie-Dick Test Card and 3M™ Attest™ eBowie-Dick Card Holder is designed for testing air removal efficiency of 132-135°C (270-275°F) dynamic-air-removal steam sterilizers with chamber volumes greater than 54L (approximately 2 cubic feet).
>
> 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.

The probable benefits outweigh the probable risks for the 3M™ Attest™ eBowie-Dick Test. The device provides benefits, and the risks can be mitigated using general controls and the identified special controls.

CONCLUSION

The De Novo request for the 3M™ Attest™ eBowie-Dick Test is granted and the device is classified as follows:

> Product Code: SBE

Device Type: Digital physical/chemical sterilization process sensor
Regulation Number: 21 CFR 880.2801
Class: II