September 13, 2019

Sterilucent, Inc.
Peter Kalkbrenner
Director of Engineering
1400 Marshall St. NE
Minneapolis, Minnesota 55413

Re: K190005
Trade/Device Name: Sterilucent HC 80TT Hydrogen Peroxide Sterilizer
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: August 8, 2019
Received: August 13, 2019

Dear Peter Kalkbrenner:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) 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 Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K190005

Device Name
Sterilucent HC 80TT Hydrogen Peroxide Sterilizer

Indications for Use *(Describe)*
Indications for Use:
The Sterilucent HC 80TT Hydrogen Peroxide Sterilizer is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The two pre-programmed sterilization cycles, the Lumen Cycle and the Flexible Cycle, operate at low pressure and low temperature and are thus suitable for processing medical devices that are sensitive to heat and moisture.

The HC 80TT Lumen Cycle can sterilize:

- o Lumen and non-lumen medical devices with diffusion-restricted spaces or mated surfaces such as the hinged portion of forceps and scissors;
- o Single or dual channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are:
  - ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm long, or
  - ≥ 1.33 mm ID and ≤ 430 mm long; and,
- o Triple channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are:
  - ≥ 1.00 mm ID and ≤ 310 mm long.

The validation testing for all lumen sizes was conducted using a maximum of fifteen (15) lumens per load. Hospital loads should not exceed the maximum number oflumens validated by this testing. The validation studies were performed using two (2) separate validation loads as described in the following table.

HC 80TT Lumen Cycle Validation Load Descriptions		
Load #	**Description**	**Load Weight[1]**
1	Two wrapped trays with silicone mats, one (1) triple channel hysteroscope, three (3) dual channel rigid ureteroscopes, six (6) suction tubes (15 total lumens), and general medical instruments such as clamps, forceps, shears, mallets, scissors and retractors.	20.2 lb.
2	Wrapped heavy drill set with ten (10) lumens and pouched batteries.	28.1 lb.

[1] Excluding the weight of the wrap.

1 Excluding the weight ofthe wrap.

The HC 80TT Flexible Cycle can sterilize:

- Rigid or semi-rigid non-lumen medical devices including non-lumen devices with metallic diffusion-restricted spaces such or mated surfaces such as the hinged portion of forceps or scissors;
- Single channel flexible endoscopes with flexible lumens that are:
  - ≥ 1.00 mm ID and ≤ 1280 mm long; and,
- Dual channel flexible endoscopes with flexible lumens that are:
  - 2: 0.80 mm ID and :S 1000 mm long.

The validation studies were performed using four (4) separate validation loads as described in the following table.

HC 80TT Flexible Cycle Validation Load Descriptions		
Load #	**Description**	**Load Weight[1]**
1	Two wrapped trays with silicone mats, one (1) single channel flexible angioscope (1.0mm ID x 1280mm L), one (1) single channel flexible ureteroscope (1.2mm ID x 800mm L), and general medical instruments such as clamps, forceps, shears, rongeurs, mallets, scissors, retractors and spreaders.	31.9 lb.
2	Two wrapped trays with silicone mats and general medical instruments such as clamps, forceps, shears, rongeurs, mallets, scissors, retractors and spreaders.	30.6 lb.
3	Two wrapped trays with silicone mats, one with one (1) dual channel flexible ureteroscope (1.2/0.8 mm ID x 850/1000 mm L) with light cord and accessories, the other with one (1) single channel flexible angioscope (1.0mm ID x 1280mm L) with light cord.	14.4 lb.
4	Two wrapped trays, one with a silicone mat and general medical instruments such as forceps, shears, mallets, and retractors, the other with eight (8) batteries.	17.6 lb.

[1] Excluding the weight of the wrap.

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)

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510(K) SUMMARY

Submitted by:	Sterilucent, Inc. 1400 Marshall Street NE Minneapolis, MN 55413 Phone: 612-767-3260 Fax: 612-767-3261
Contact Person:	Peter R. Kalkbrenner Director of Engineering peter.kalkbrenner@sterilucent.com Phone: 612-767-3253 Fax: 612-767-3261
Date of Summary:	September 11, 2019
Device Trade Name:	Sterilucent HC 80TT Hydrogen Peroxide Sterilizer
Common or Usual Name:	Vapor Phase Hydrogen Peroxide Sterilizer
Classification:	21 CFR 880.6860
Class:	II
Product Code:	MLR
Predicate Device(s):	Sterilucent PSD-85 Hydrogen Peroxide Sterilizer (K140464)
Device Description:	The Sterilucent HC 80TT Hydrogen Peroxide Sterilizer (HC 80TT) is a self-contained standalone device, using vaporized hydrogen peroxide as the sterilant. The HC 80TT is intended for use in the terminal sterilization of cleaned, rinsed, and dried, reusable metal and non-metal medical device used in healthcare facilities. The sterilization cycle operates at low pressure and temperatures and is therefore suitable for processing medical devices that are sensitive to heat and moisture. The hydrogen peroxide vapor is generated by heating aqueous hydrogen peroxide and injecting into a chamber.
Indications for Use:	The Sterilucent HC 80TT Hydrogen Peroxide Sterilizer is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The two pre-programmed sterilization cycles, the Lumen Cycle and the Flexible Cycle, operate at low pressure and low temperature and are thus suitable for processing medical devices that are sensitive to heat and moisture. The HC 80TT Lumen Cycle can sterilize: • Lumen and non-lumen medical devices with diffusion-restricted spaces or mated surfaces such as the hinged portion of forceps and scissors;

- Single or dual channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are:
  - ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm long, or
  - ≥ 1.33 mm ID and ≤ 430 mm long; and,
- Triple channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are:
  - ≥ 1.00 mm ID and ≤ 310 mm long.

The validation testing for all lumen sizes was conducted using a maximum of fifteen (15) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using two (2) separate validation loads as described in the following table.

HC 80TT Lumen Cycle Validation Load Descriptions

Load #	Description	Load Weight[1]
1	Two wrapped trays with silicone mats, one (1) triple channel hysteroscope, three (3) dual channel rigid ureteroscopes, six (6) suction tubes (15 total lumens), and general medical instruments such as clamps, forceps, shears, mallets, scissors and retractors.	20.2 lb.
2	Wrapped heavy drill set with ten (10) lumens and pouched batteries.	28.1 lb.

[1] Excluding the weight of the wrap.

The HC 80TT Flexible Cycle can sterilize:
Rigid or semi-rigid non-lumen medical devices including non-lumen devices with metallic diffusion-restricted spaces such or mated surfaces such as the hinged portion of forceps or scissors;

- Single channel flexible endoscopes with flexible lumens that are:
  - ≥ 1.00 mm ID and ≤ 1280 mm long; and,
- Dual channel flexible endoscopes with flexible lumens that are:
  - ≥ 0.80 mm ID and ≤ 1000 mm long.

The validation studies were performed using four (4) separate validation loads as described in the following table.

<table>
<tr>
<td></td>
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<table>
<tr><th colspan="3">HC 80TT Flexible Cycle Validation Load Descriptions</th></tr>
<tr><th>Load #</th><th>Description</th><th>Load Weight[1]</th></tr>
<tr><td>1</td><td>Two wrapped trays with silicone mats, one (1) single channel flexible angioscope (1.0mm ID x 1280mm L), one (1) single channel flexible ureteroscope (1.2mm ID x 800mm L), and general medical instruments such as clamps, forceps, shears, rongeurs, mallets, scissors, retractors and spreaders.</td><td>31.9 lb.</td></tr>
<tr><td>2</td><td>Two wrapped trays with silicone mats and general medical instruments such as clamps, forceps, shears, rongeurs, mallets, scissors, retractors and spreaders.</td><td>30.6 lb.</td></tr>
<tr><td>3</td><td>Two wrapped trays with silicone mats, one with one (1) dual channel flexible ureteroscope (1.2/0.8 mm ID x 850/1000 mm L) with light cord and accessories, the other with one (1) single channel flexible angioscope (1.0mm ID x 1280mm L) with light cord.</td><td>14.4 lb.</td></tr>
<tr><td>4</td><td>Two wrapped trays, one with a silicone mat and general medical instruments such as forceps, shears, mallets, and retractors, the other with eight (8) batteries.</td><td>27.7 lb.</td></tr>
</table>
[1] Excluding the weight of the wrap.
</td>
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<tr>
<td>Technological Characteristics</td>
<td>The Sterilucent HC 80TT Hydrogen Peroxide Sterilizer (HC 80TT) is compared to the predicate device Sterilucent PSD-85 Hydrogen Peroxide Sterilizer (K140464) using the information supplied below.</td>
</tr>
</table>

	Subject Device: **Sterilucent HC 80TT Hydrogen Peroxide Sterilizer (HC 80TT)**	**Predicate Device (K140464):** **Sterilucent PSD-85 Hydrogen Peroxide Sterilizer (PSD-85)**
Classification	21 CFR 880.6860	21 CFR 880.6860
Product Code	MLR	MLR
Indications for Use	The Sterilucent HC 80TT Hydrogen Peroxide Sterilizer is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The two pre-programmed sterilization cycles, the Lumen Cycle and the Flexible Cycle, operate at low pressure and low temperature and are thus suitable for processing medical devices that are sensitive to heat and moisture. The HC 80TT Lumen Cycle can sterilize: • Lumen and non-lumen medical devices with diffusion-restricted spaces or mated surfaces such as the hinged portion of forceps and scissors; • Single or dual channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are: o ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm long, or o ≥ 1.33 mm ID and ≤ 430 mm long; and, • Triple channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are: o ≥ 1.00 mm ID and ≤ 310 mm long. The validation testing for all lumen sizes was conducted using a maximum of fifteen (15) lumens per load. Hospital loads	The Sterilucent PSD-85 Hydrogen Peroxide Sterilizer (PSD-85) is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The two pre-programmed sterilization cycles, the Lumen and the Non-Lumen Cycles, operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture. The PSD-85 Lumen Cycle can sterilize*: • Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices with a single stainless steel lumen with: o An inside diameter of 1 mm or larger and a length of 60 mm or shorter o An inside diameter of 2 mm or larger and a length of 250 mm or shorter o An inside diameter of 3 mm or larger and a length of 350 mm or shorter

should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using two (2) separate validation loads as described in the following table.

HC 80TT Lumen Cycle Validation Load Descriptions		
Load #	**Description**	**Load Weight**[1]
1	Two wrapped trays with silicone mats, one (1) triple channel hysteroscope, three (3) dual channel rigid ureteroscopes, six (6) suction tubes (15 total lumens), and general medical instruments such as clamps, forceps, shears, mallets, scissors and retractors.	20.2 lb.
2	Wrapped heavy drill set with ten (10) lumens and pouched batteries.	28.1 lb.

[1] Excluding the weight of the wrap.

The HC 80TT Flexible Cycle can sterilize:

- Rigid or semi-rigid non-lumen medical devices including non-lumen devices with metallic diffusion-restricted spaces such or mated surfaces such as the hinged portion of forceps or scissors;
- Single channel flexible endoscopes with flexible lumens that are:
  - ≥ 1.00 mm ID and ≤ 1280 mm long; and,
- Dual channel flexible endoscopes with flexible lumens that are:
  - ≥ 0.80 mm ID and ≤ 1000 mm long.

*The validation testing for all lumen sizes was conducted using a maximum of ten (10) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of one instrument tray with a total weight of 10.4 lbs.

The PSD-85 Non-Lumen Cycle can sterilize**:

- Non-lumen instruments including non-lumen instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors.

**The validation studies were conducted using a validation load consisting of one instrument tray with a total weight of
25.3 lbs.

The validation studies were performed using four (4) separate validation loads as described in the following table.

HC 80TT Flexible Cycle Validation Load Descriptions

Load #	Description	Load Weight[1]
1	Two wrapped trays with silicone mats, one (1) single channel flexible angioscope (1.0mm ID x 1280mm L), one (1) single channel flexible ureteroscope (1.2mm ID x 800mm L), and general medical instruments such as clamps, forceps, shears, rongeurs, mallets, scissors, retractors and spreaders.	31.9 lb.
2	Two wrapped trays with silicone mats and general medical instruments such as clamps, forceps, shears, rongeurs, mallets, scissors, retractors and spreaders.	30.6 lb.
3	Two wrapped trays with silicone mats, one with one (1) dual channel flexible ureteroscope (1.2/0.8 mm ID x 850/1000 mm L) with light cord and accessories, the other with one (1) single channel flexible angioscope (1.0mm ID x 1280mm L) with light cord.	14.4 lb.
4	Two wrapped trays, one with a silicone mat and general medical	27.7 lb.

	instruments such as forceps, shears, mallets, and retractors, the other with eight (8) batteries. [1] Excluding the weight of the wrap.	
Single Use/Reusable	Reusable	Reusable
Type of Process	Terminal Sterilization	Terminal Sterilization
Sterility Assurance Level	10^{-6}	10^{-6}
Sterilant	59% aqueous solution of hydrogen peroxide (H_2O_2)	59% aqueous solution of hydrogen peroxide (H_2O_2)
Sterilization Cycles	Two pre-programmed cycles: Lumen (approximately 65 min) and Flexible (approximately 35 min)	Two pre-programmed cycles: Lumen (approximately 72 min) and Non-Lumen (approximately 40 min)
Physical Characteristics	Self-contained, stand-alone device	Self-contained, stand-alone device
Design and Construction	Welded frame onto which is mounted the sterilization chamber along with a variety of instruments and components, controls, piping, and vacuum pump, all of which is housed in an enclosed frame	Welded frame onto which is mounted the sterilization chamber along with a variety of instruments and components, controls, piping, and vacuum pump, all of which is housed in an enclosed frame
• Chamber Volume	80 L	85 L
• Weight	306 lbs (139 kg)	440 lbs (200 kg)
• Maximum Power	2400 Watts	1650 Watts
Overall design	Deep vacuum sterilizer Firmware controlled, non-programmable Single door Two shelves	Deep vacuum sterilizer Firmware controlled, non-programmable Single door One shelf
Chamber Materials	Aluminum	Stainless steel
Chamber Heating system	Electric silicone-rubber resistive heaters	Electric silicone-rubber resistive heaters
Internal Process Monitors		

• Temperature	Chamber and vaporizer thermistors	Chamber and vaporizer thermistors
• Pressure	Chamber pressure transducers	Chamber pressure transducers
• Sterilant Concentration	Real-time hydrogen peroxide vapor monitor	Real-time hydrogen peroxide vapor monitor
User Interface	7 inch capacitive touch thin-film-transistor (TFT) liquid-crystal display (LCD) graphical user interface (GUI)	40 character x 4 line dot matrix liquid crystal display (LCD)
External Process Monitors	• Electronic controls • USB port for communicating with separate computer • Printer	• Electronic controls • USB port for communicating with separate computer
Operational Principle	Sterilization of the intended devices by exposure under controlled conditions of pressure, temperature, and time	Sterilization of the intended devices by exposure under controlled conditions of pressure, temperature, and time
Operational Parameters	Low pressure and temperature	Low pressure and temperature
Pre-processing requirements	Cleaned, rinsed and dried medical devices	Cleaned, rinsed and dried medical devices
Amount of sterilant per injection	Variable, based on actual measured vapor concentration	Variable, based on actual measured vapor concentration
Monitoring – biological and chemical indicators		
• Biological Indicator	Self-contained biological indicator, *Geobacillus stearothermophilus*	Self-contained biological indicator, *Geobacillus stearothermophilus*
• Process Challenge Device/Routine Test Pack	Self-contained biological indicator, *Geobacillus* stearothermophilus	Self-contained biological indicator, *Geobacillus stearothermophilus*
• Chemical Indicator	Sterilucent CI Strips, Labels	Sterilucent CI Strips, Labels and Tape
Miscellaneous		
Materials Sterilized	Reusable metal and non-metal medical devices that are used in healthcare facilities, including those that are sensitive to heat and moisture	Reusable metal and non-metal medical devices that are used in healthcare facilities, including those that are sensitive to heat and moisture

Comparison to the Predicate device:

Both the HC 80TT and the predicate device have the same:

- Intended use
- Processes validated to a Sterility assurance level (10^{-6})
- Sterilant

The HC 80TT design differs slightly from the predicate; the HC 80TT is slightly smaller and lighter that the PSD-85.

Using the Lumen Cycle, the HC 80TT can sterilize single-, dual-, or triple-channeled rigid and semi-rigid endoscopes with stainless steel lumens as specified in the Indications for Use, while the PSD-85 is indicated to sterilize medical devices with only a single stainless-steel lumen of larger diameter and shorter length. The HC 80TT's "Flexible Cycle" and the PSD-85's "Non-Lumen Cycle" both sterilize non-lumen instruments with diffusion-restricted spaces, but the HC 80TT is also indicated to sterilize single- and dual-channel flexible endoscopes.

Performance Testing (Bench):

The HC 80TT sterilization cycle parameters have been shown to provide a level of safety and efficacy at least equivalent to that of the predicate device. Testing was performed using the "overkill" method.

Pre-Validation Testing

Test Organism: *Geobacillus stearothermophilus*

Process Variables and Parameters

Testing was conducted to characterize the effect of process parameters on lethality. The four critical process parameters are chamber wall temperature, vaporizer temperature, injection pressure and vaporized hydrogen peroxide concentration. The level tested for each parameter was selected to provide a worst-case situation for the test series and to be outside the abort levels or settings for the sterilizer. The study showed that process lethality was unaffected over the range of tested process parameters.

HC 80TT Sterilization Process Validation

Demonstration of Dose-Response Relationship to Increasing Hydrogen Peroxide Concentration

Dose response testing was performed using various materials (representative of materials used in medical devices) as spore carriers.

Geobacillus stearothermophilus death kinetics data obtained for each material tested demonstrate a positive "dose response" to increasing concentration of hydrogen peroxide injected under half cycle conditions in the HC 80TT. There were no spore survivors on any material at concentrations lower than the standard exposure concentration for the Lumen and Flexible Cycles. The result

demonstrates that the dose response observed is not limited to a single substrate and in each case >6 Spore Log Reduction (SLR) was observed for a half cycle exposure.

Surface Sterilization

The purpose of the study was to demonstrate sterilization of medical device surfaces. *Geobacillus stearothermophilus* spores were inoculated on a wide variety of material coupons that were representative of materials used in re-usable medical devices. The coupons were inoculated with at least 10^6 *Geobacillus stearothermophilus* spores and then exposed to ½ cycle sterilization parameters.

Results from this testing demonstrate a Sterility Assurance Level (SAL) of at least 10^{-6} for medical device surface sterilization in the HC 80TT for all materials listed as recommended for use in the HC 80TT.

Mated Surface Sterilization

The purpose of the study was to demonstrate sterilization of mated medical device surfaces using the HC 80TT. *Geobacillus stearothermophilus* spores were inoculated on a variety of medical device materials. The materials were than mated to the same material and exposed to ½ cycle sterilization parameters. An SAL of least 10^{-6} was demonstrated for mated material sterilization.

Lumen Sterilization

The purpose of this validation test was to demonstrate that the HC 80TT could effectively sterilize specific dimensions of rigid stainless steel and flexible lumened medical devices. Testing was completed by placing at least 10^{-6} *Geobacillus stearothermophilus* spores in the center of the lumens and exposing them to ½ cycle sterilization parameters. There were no spore survivors after multiple ½ cycle exposure tests.

Results from this testing demonstrate an SAL of at least 10^{-6} for lumen sterilization in the HC 80TT for the lumen dimensions listed as indicated for use in the HC 80TT.

Simulated Use Testing

Simulated use testing was performed to confirm sterilization of medical device surfaces and lumens after processing in the HC 80TT. Representative lumen and non-lumen devices were inoculated with at least 10^{-6} *Geobacillus stearothermophilus* spores, suspended in an inorganic and organic challenge soil and exposed to a full sterilization cycle. The results showed sterility of all tested devices.

In-Use Testing

Devices representative of surface features and lumen claims for the HC 80TT were selected for sterility testing. Devices including stainless steel devices with open surfaces, mated or hinged surfaces, representative stainless steel lumen devices, and representative flexible scopes were soiled with clinical soils. The soiled devices were manually cleaned and/or washed per the Manufacturer's Instructions for Use, dried, packaged and processed in the applicable HC 80TT cycle (Lumen or Flexible). The results of the in-use testing demonstrated that the HC 80TT successfully sterilizes surgical instruments used in clinical settings.

Supporting Microbiological Testing

Sterilizing agent efficacy (Sporicidal Activity of a Disinfectant) testing was performed in the HC 80TT in accordance with the guidelines provided in AOAC Official Method 966.04, *Sporicidal Activity of Disinfectants*. None of the carriers demonstrated growth.

Software Validation

Software validation was performed according to FDA's moderate level of concern recommendations provided in the document "Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices".

Conclusion:

The nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.