DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 31, 2017

Steris Corporation
Bill Brodbeck
Director, Regulatory Affairs
5960 Heisley Rd
Mentor, Ohio 44060

Re: K162413
Trade/Device Name: Amsco® V-PRO™ 1 Low Temperature Sterilization System
Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System
V-PRO™ Max Low Temperature Sterilization System
V-PRO 60 Low Temperature Sterilization System
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: February 21, 2017
Received: February 22, 2017

Dear Bill Brodbeck:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162413

Device Name
V-PRO® 1, V-PRO® 1 Plus and V-PRO® maX Low Temperature Sterilization Systems

Indications for Use *(Describe)*
The V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems, with VAPROX® HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in healthcare facilities. The pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' Lumen Cycle can sterilize:(a)

- Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: (a)
  - o single channeled devices with a stainless lumen that is ≥ 0.77 mm internal diameter (ID) and ≤ 500 mm in length
  - o dual channeled devices with stainless steel lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length
  - o triple channeled devices with stainless steel lumens that are
    - ≥ 1.2 mm ID and ≤ 275 mm in length
    - ≥ 1.8 mm ID and ≤ 310 mm in length
    - or
    - ≥ 2.8 mm ID and ≤ 317 mm in length

(a) The validation studies for all channel/lumen configurations were conducted using a maximum of twenty (20) 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 two instrument trays and two pouches for a total weight of 19.65 lbs.

The V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' Non Lumen Cycle can sterilize: (b)
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless steel or titanium diffusion-restricted areas such as the hinged portion of forceps or scissors.

(b) The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs.

The V-PRO maX Low Temperature Sterilization System's Flexible Cycle can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of two load configurations:

1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load. (c)
   The flexible endoscopes may contain either:
   - a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
   - or two lumens with:
     - one lumen that is ≥ 1 mm ID and ≤ 990 mm in length
     - and the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length

(c) The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.(d) The flexible endoscope can contain either:
   - a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
   - or two lumens with:
     - one lumen that is ≥ 1 mm ID and ≤ 990 mm in length
     - and the other lumen that is ≥ 1 mm and ≤ 850 mm in length

   (d) The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total load weight of 24.0 lbs.

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)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162413

Device Name
V-PRO® 60 Low Temperature Sterilization System

Indications for Use *(Describe)*
The V-PRO 60 Low Temperature Sterilization System, with VAPROX® HC Sterilant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in Healthcare facilities. The pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The V-PRO 60 Sterilizer's Lumen Cycle can sterilize: (a)

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Non-lumened devices including non-lumened rigid and semi-rigid endoscopes
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: (a)
  - single or dual lumen devices with stainless steel lumens that are ≥ 0.77 mm (~1/32") internal diameter (ID) and ≤ 410 mm (16-9/64") in length
  - triple lumen devices with stainless steel lumens that are
    - ≥ 1.2 mm (~3/64") ID and ≤ 275 mm (~10-55/64") in length
    - ≥ 1.8 mm (~5/64") ID and ≤ 310 mm (~12-13/64") in length

    or
    - ≥ 2.8 mm (~7/64") ID and ≤ 317 mm (12-31/64") in length

(a) The validation studies for all lumen configurations were conducted using a maximum of twelve (12) 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 instrument organizers and mat and two pouches for a total weight of 11 lbs (5.0 kg).

The V-PRO 60 Sterilizer's Non Lumen Cycle can sterilize (b)

- Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.

(b) The validation studies were performed using a validation load consisting of one instrument tray with instrument organizers and mat and one pouch for a total weight of 12 lbs (5.4 kg).

The V-PRO 60 Sterilizer's Flexible Cycle can sterilize: (c)

- One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a:
  - single or dual lumen device with lumens that are > 1 mm (~3/64") ID and < 990 mm (38-63/64") in length

(c) The validation studies were conducted with one flexible endoscope, packaged into a tray with silicone mat, instrument organizers and light cord (if not integral to scope) and no additional load.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
For
Amsco V-PRO 1 Low Temperature Sterilization System
Amsco V-PRO 1 Plus Low Temperature Sterilization System
V-PRO maX Low Temperature Sterilization System
V-PRO 60 Low Temperature Sterilization System

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Contact: Bill Brodbeck
Director, Regulatory Affairs
Tel: 440-392-7690
Fax: 440-357-9198

Summary Date: March 31, 2017

1. Device Name

Trade Name: Amsco® V-PRO™ 1 Low Temperature Sterilization System
Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System
V-PRO™ maX Low Temperature Sterilization System
V-PRO 60 Low Temperature Sterilization System

Device Class:	Class II
Common/usual Name:	Vapor Phase Hydrogen Peroxide Sterilizer
Classification Name:	Sterilizer, Ethylene Oxide Gas
Classification Number:	21 CFR 880.6860
Product Code:	MLR

2. Predicate Device

The claimed primary predicate device is the V-PRO maX Low Temperature Sterilization System, cleared most recently under **K160433**.

Reference Devices are included in this submission as the V-PRO maX cleared indications for use includes claims for the following proposed reference devices:

- Amsco® V-PRO™ 1 Low Temperature Sterilization System (**K062297**)
- Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System (**K083097**, **K102394** and **K111810**)

The V-PRO™ maX Low Temperature Sterilization System prior clearances include Premarket Submissions **K102330**, **K112760**, **K112813**, **K120632** and **K131120**.

V-PRO 60 Low Temperature Sterilization System, cleared most recently under **K140498**.

The purpose of this submission is to remove labeling restrictions of processing eye-contacting devices which contain certain materials and to include polyurethane as a material compatible while being processed in the devices' Lumen Cycle.

3. Description of Device

The V-PRO 1, V-PRO 1 Plus, V-PRO maX and V-PRO 60 Low Temperature Sterilization Systems, with VAPROX® HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in healthcare facilities. The Sterilizers use VAPROX® HC Sterilant to sterilize the intended devices through

exposure to vaporized hydrogen peroxide (VHP). The packaged sterilized devices are ready for use at the completion of the cycle; no cool down or aeration period is required following completion of the cycle.

The V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems are programmed to enact one (the Lumen Cycle), two (the Lumen Cycle and the Non Lumen Cycle) or three (the Lumen Cycle, the Non Lumen Cycle and the Flexible Cycle) cycles, respectively.

The V-PRO 60 Low Temperature Sterilization System, with VAPROX® HC Sterilant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in healthcare facilities. The three pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

4. Intended Use

The V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems, with VAPROX® HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in healthcare facilities. The pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' Lumen Cycle can sterilize:(a)

• Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors

• Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: (a)

o single channeled devices with a stainless lumen that is ≥ 0.77 mm internal diameter (ID) and ≤ 500 mm in length

o dual channeled devices with stainless steel lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length o triple channeled devices with stainless steel lumens that are

≥ 1.2 mm ID and ≤ 275 mm in length

≥ 1.8 mm ID and ≤ 310 mm in length or

≥ 2.8 mm ID and ≤ 317 mm in length

(a) The validation studies for all channel/lumen configurations were conducted using a maximum of twenty (20) 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 two instrument trays and two pouches for a total weight of 19.65 lbs.

The V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' Non Lumen Cycle can sterilize: (b) Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless steel or titanium diffusion-restricted areas such as the hinged portion of forceps or scissors.
(b) The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs.

The V-PRO maX Low Temperature Sterilization System's Flexible Cycle can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of two load configurations:
1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load. (c) The flexible endoscopes may contain either:
• a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
• or two lumens with:
• one lumen that is ≥ 1 mm ID and ≤ 990 mm in length
• and the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length
(c) The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.(d) The flexible endoscope can contain either:

• a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
• or two lumens with:
• one lumen that is ≥ 1 mm ID and ≤ 990 mm in length
• and the other lumen that is ≥ 1 mm and ≤ 850 mm in length
(d) The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total load weight of 24.0 lbs.

The V-PRO 60 Low Temperature Sterilization System, with VAPROX® HC Sterilant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried metal and nonmetal medical devices used in Healthcare facilities. The pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The V-PRO 60 Sterilizer's Lumen Cycle can sterilize: (a)

• Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
• Non-lumened devices including non-lumened rigid and semi-rigid endoscopes

• Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: (a)
- single or dual lumen devices with stainless steel lumens that are ≥ 0.77 mm (~1/32") internal diameter (ID) and
≤ 410 mm (16-9/64") in length
- triple lumen devices with stainless steel lumens that are
• ≥ 1.2 mm (~3/64") ID and ≤ 275 mm (~10-55/64") in length
• ≥ 1.8 mm (~5/64") ID and ≤ 310 mm (~12-13/64") in length or
• ≥ 2.8 mm (~7/64") ID and ≤ 317 mm (12-31/64") in length

(a) The validation studies for all lumen configurations were conducted using a maximum of twelve (12) 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 instrument organizers and mat and two pouches for a total weight of 11 lbs (5.0 kg).

The V-PRO 60 Sterilizer's Non Lumen Cycle can sterilize (b)

• Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.

(b) The validation studies were performed using a validation load consisting of one instrument tray with instrument organizers and mat and one pouch for a total weight of 12 lbs (5.4 kg).

The V-PRO 60 Sterilizer's Flexible Cycle can sterilize: (c)

• One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a:
- single or dual lumen device with lumens that are > 1 mm (~3/64") ID and < 990 mm (38-63/64") in length

(c) The validation studies were conducted with one flexible endoscope, packaged into a tray with silicone mat, instrument organizers and light cord (if not integral to scope) and no additional load.

5. Description of Safety and Substantial Equivalence

The V-PRO 1, V-PRO 1 Plus, V-PRO maX and V-PRO 60 Sterilizers are the same as the predicate devices except for the specific requested changes to labeling as described in this submission. There are no differences in the indications for use or technology (including features, materials, and principles of operation) between the proposed and predicate devices. Therefore, the differences between the proposed and predicate devices are limited to the proposed changes to labeling to remove

eye-contacting materials restrictions and add polyurethane as a compatible material for processing in the devices' Lumen Cycle.

The following table summarizes the verification activity that was performed with its respective acceptance criteria to ensure that this modification does not affect the safety or effectiveness of the V-PRO 1, V-PRO 1 Plus, V-PRO maX or V-PRO 60 Low Temperature Sterilization Systems.

Device Modification	Verification / Validation Activity	Results
Removal of Eye-Contacting Limitations from the V-PRO Low Temperature Sterilization Systems	Compare the residual hydrogen peroxide level for materials after processing under worst case conditions in the V-PRO Sterilizers and the STERRAD 100NX Sterilizer	**Pass** V-PRO 60 Sterilizer (worst-case) processed samples hydrogen peroxide residues were statistically less than or equal to materials similarly processed in the STERRAD 100NX Sterilizer.
	Compare the dilution required to achieve non-cytotoxic results for materials after processing under worst case conditions in the V-PRO Sterilizers and the STERRAD 100NX Sterilizer. Confirm that the cytotoxic component present in each extract (if the neat sample is cytotoxic) is hydrogen peroxide (H_2O_2) by the addition of catalase to the extracts.	**Pass** The cytotoxic response for all materials processed in the V-PRO 60 Sterilizer cycles (worst-case) was equivalent to or less than the cytotoxic response for the same materials processed in STERRAD 100NX Sterilizer Cycles. The cytotoxic component for all V-PRO 60 Sterilizer (worst-case) processed materials was identified as hydrogen peroxide (H_2O_2).
	Determine the cytotoxicity for medical devices after processing in three (3) back-to-back V-PRO 60 Sterilizer (worst-case) Lumen Cycles.	**Pass** Following exposure to three (3) back-to-back cycles, devices are non-cytotoxic at the neat dilution.
	Compare the residual hydrogen peroxide level for medical devices after processing in three (3) back-to-back V-PRO 60 Sterilizer (worst-case) Lumen Cycles to hydrogen peroxide levels known to cause eye biocompatibility concerns.	**Pass** Following exposure to three (3) back-to-back cycles, device hydrogen peroxide residues are below levels known to cause biocompatibility concerns.
	Evaluate V-PRO Sterilizer materials processed for 3 consecutive cycles for ocular irritation per ISO 10993-10.	**Pass** Materials coupons processed for 3 consecutive cycles in the V-PRO maX Lumen (worst-case) Cycle are non-irritants per ISO 10993-10 evaluation.

Device Modification	Verification / Validation Activity	Results
Addition of polyurethane as a compatible material for V-PRO Sterilizers' Lumen Cycle	Evaluate polyurethane material compatibility after processing the worst case V-PRO Sterilizer Cycle.	**Pass** No material degradation or cosmetic changes were observed for the polyurethane-containing device.
	Sterilization efficacy for polyurethane in Lumen Cycle is demonstrated by previously completed testing in the V-PRO maX and V PRO 60 Sterilizers' (worst-case) Non Lumen Cycle	**Pass**

6. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and perform at least as safely and effectively as the legally marketed predicate device (K160433), Class II (21 CFR 880.6860), product code MLR.