February 2, 2023

Steelco S.P.A.
% Jonathan Wilder
President
H & W Technology, LLC
301 City Ave. Suite LL3
Bala Cynwyd, PA 19004

Re: K213545
Trade/Device Name: Steelco VS Series Steam Sterilizers, models 262839, 262851, 262869
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: December 16, 2022
Received: January 3, 2023

Dear Jonathan Wilder:

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,

Clarence W. Murray III -S

Clarence W. Murray, III, Ph.D
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213545

Device Name
Steelco VS Series Steam Sterilizers, models 262839, 262851, 262869.

Indications for Use *(Describe)*
The Steelco VS Series Steam Sterilizers are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are equipped with twelve factory-programmed cycles, provided on the following page.

At no time will there be patient contact with the subject device.

Please see page 2 for indications for use defining available, preprogrammed 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.

Standard cycles pre-programmed at factory

Cycles	Sterilization temperature	Sterilization time	Dry time	Maximum recommended load
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Load Table for recommended quantities.
Prevac	275°F (135°C)	3 minutes	30 minutes	
Prevac - IUSS	270°F (132°C)	4 minutes	1 minutes	Immediate use – single unwrapped tray, nonporous items
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Load Table for recommended quantities.
Gravity	270°F (132°C)	15 minutes	30 minutes	
Gravity	275°F (135°C)	15 minutes	30 minutes	
Gravity - IUSS	270°F (132°C)	10 minutes	1 minute	Immediate use – single unwrapped tray, nonporous items
Warm-up	270°F (132°C)	N/A	N/A	N/A
Bowie - Dick	270°F (132°C)	3.5 minutes	5 minute	Bowie-Dick Test Pack, DART Test Pack
Leak test	N/A	N/A	N/A	N/A

The maximum loads and dimensions of the sterilizer for each of the sterilizer models are shown in the following table:

Dimensions and Load Capacity

Internal Chamber Dimensions	Overall dimensions	Number of trays/fabric packs for maximum load
26 x 28 x 39”	37.4 x 94.5 x 50.9”	9/18
26 x 28 x 51”	37.4 x 94.5 x 62.7”	12/24
26 x 28 x 69”	37.4 x 94.5 x 80.4”	15/30

510(k) Summary for Steelco VS Steam Sterilizers K213545

SUBMITTER: Steelco S.P.A.
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DATE PREPARED: January 31, 2023

TRADE NAME: Steelco VS Series Steam Sterilizers, models 262839, 262851, 262869

COMMON NAME: Steam Sterilizer

DEVICE CLASSIFICATION: Class II

DEVICE Steam Sterilizer

PANEL: General Hospital

CLASSIFICATION NAMES: Steam Sterilizer, 21 CFR 880.6880, classification code FLE

PREDICATE DEVICES: AMSCO 600 Steam Sterilizer K183410

DEVICE DESCRIPTION: The Steelco VS Series Steam Sterilizers use saturated steam, generated from a house steam utility (e.g. boiler system) or from a steam generator, to sterilize heat-stable health care products.

The sterilizer accomplishes this by removing the air in the chamber, exposing the load to saturated steam for a defined combination of time and temperature, and drying the load. Removal of air from the chamber occurs using either of two methods, gravity displacement or mechanical vacuum. Once the air removal phase is completed, the sterilizer progresses to the steam exposure phase. During the steam exposure phase, every surface of the load is exposed to saturated steam for a defined combination of time and temperature. Once the steam exposure phase is completed, steam is removed from the chamber and the load is dried using the latent heat in the load and the vacuum pump.

The sterilizers are generally operated by technicians in a central service or sterile processing department of healthcare facilities. Sterilizers may also be located in a surgical suite to allow for Immediate Use Steam Sterilization (IUSS) for instances where an instrument is needed immediately for a procedure (e.g. after an instrument has been dropped and there is no replacement readily available). Standard practices for use of sterilizers in health care facilities are provided by various organizations (e.g. ANSI/AAMI ST79).

INTENDED USE/INDICATIONS FOR USE:
At no time will there be patient contact. The Steelco VS Series Steam Sterilizers are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are equipped with twelve factory-programmed cycles, shown in the table below:

Standard cycles pre-programmed at factory

Cycles	Sterilization temperature	Sterilization time	Dry time	Maximum recommended load
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Load Table for recommended quantities.
Prevac	275°F (135°C)	3 minutes	30 minutes	
Prevac - IUSS	270°F (132°C)	4 minutes	1 minutes	Immediate use – single unwrapped tray, nonporous items
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. Refer to Load Table for recommended quantities.
Gravity	270°F (132°C)	15 minutes	30 minutes	
Gravity	275°F (135°C)	15 minutes	30 minutes	
Gravity - IUSS	270°F (132°C)	10 minutes	1 minute	Immediate use – single unwrapped tray, nonporous items
Warm-up	270°F (132°C)	N/A	N/A	N/A
Bowie-Dick	270°F (132°C)	3.5 minutes	5 minute	Bowie-Dick Test Pack, DART Test Pack
Leak test	N/A	N/A	N/A	N/A

The maximum loads and dimensions of the sterilizer for each of the sterilizer models are shown in the following table:

Dimensions and Load Capacity

Internal Chamber Dimensions	Overall dimensions			Number of trays/fabric packs for maximum load
	Width	Height	Depth	
26 x 28 x 39”	37.4”	94.5”	50.9”	9/18
26 x 28 x 51”	37.4”	94.5”	62.7”	12/24
26 x 28 x 69”	37.4”	94.5”	80.4”	15/30

Sterilizers are available in single-door (suffix of /1 to the model number) or double-door (suffix of /2 to the model number) configurations with double-door models interlocked to not permit both doors to be open at the same time, and to not allow release of improperly sterilized items to the sterile side of the machine.

The environment of use will be a healthcare facility's sterile processing department, or wherever else in the facility sterilizers are used.

Technological Characteristics Comparison Table

The Steelco VS Series Sterilizers are compared to the predicate device in the following table.

Feature	Steelco VS Series Steam Sterilizers (K213545)	AMSCO 600 Steam Sterilizer (predicate device K183410)	Comparison
Intended Use	The Steelco VS Series Steam Sterilizers are designed for sterilization of heat and moisture-stable materials used in healthcare facilities	The AMSCO 600 Steam Sterilizer is designed for sterilization of heat and moisture-stable materials used in healthcare facilities.	Same
Critical Process Parameters	Time, Chamber Temperature, Pressure	Time, Chamber Temperature, Pressure	Same
Control	PLC	Embedded controller	Similar
SAL	10^{-6}	10^{-6}	Same
Sterilant	Saturated steam	Saturated steam	Same
Utilities	Steam, water, electricity, air	Steam, water, electricity, air	Same
Chamber material	316 stainless steel	316L stainless steel	Similar
Nominal chamber size	26" x 28" x 39" 26" x 28" x 51" 26" x 28" x 69"	26" x 26" x 39" 26" x 26" x 49" 26" x 26" x 61"	Similar

Feature	Steelco VS Series Steam Sterilizers (K213545)	AMSCO 600 Steam Sterilizer (predicate device K183410)	Comparison
Door	316 Stainless Steel 28" x 26" Power vertical sliding	304L Stainless Steel 26" x 26" Power vertical sliding	Similar
Chamber pressure rating	44 PSIG/291°F	45 PSIG, 300°F	Similar
Door seal	Steam activated door seal	Steam activated door seal	Same
External process monitors	Independent process control and monitors Printer	Electronic Control Printer	Similar
Internal process monitors	Temperature -Dual independent temperature probes in chamber drain -Temperature probe in jacket drain -Temperature probe in cooling water reservoir tank Pressure -Dual independent pressure transducers in chamber -Pressure transducer in on-board boiler (if this option chosen)	Temperature -Dual element RTD located in chamber drain - RTD located in the jacket drain - RTD located in heat exchanger Pressure -Pressure transducer in chamber	Similar
Performance	Meets ANSI/AAMI ST8:2013	Meets ANSI/AAMI ST8:2013	Same
Accessories	Shelves, loading equipment	BI, CI, Pouches, Trays, Wraps, Tape, Containers, Shelves, Loading Equipment	Similar
Test Cycles	Warm Up, Leak Test, Bowie Dick Test	Warm Up, Leak Test, DART (Bowie Dick) Test	Same
Cycles	Prevac 270°F (132°C)/4 minutes, fabric packs Prevac 275°F (135°C)/3 minutes,	270F, Prevac, 4' Full fabric pack 270F, Prevac, 4' Full tray 270F, Prevac, 4' one fabric pack	Similar

Feature	Steelco VS Series Steam Sterilizers (K213545)	AMSCO 600 Steam Sterilizer (predicate device K183410)	Comparison
	double-wrapped instrument trays Prevac – IUSS 270°F (132°C)/4 minutes, single unwrapped tray, nonporous items Gravity 250°F (121°C)/30 minutes, double-wrapped instrument trays Gravity 270°F (132°C) 15 minutes, double-wrapped instrument trays Gravity 275°F (135°C)/10 minutes, double-wrapped instrument trays Gravity – IUSS 270°F (132°C)/10 minutes, single unwrapped tray, nonporous items	270F, Prevac, 4' IUSS 275F, Prevac, 3' Full fabric 250F, Gravity, 30' Full tray	
Full loads	• 39": 9, 25-lb double wrapped trays or 18, fabric packs • 51": 12, 25-lb double wrapped trays or 24, fabric packs • 69": 15, 25-lb double wrapped trays or 30, fabric packs	• 39": 9, 25-lb double wrapped trays or 12, fabric packs • 51": 12, 25-lb double wrapped trays or 16, fabric packs • 63": 15, 25-lb double wrapped trays or 20, fabric packs	Similar

The proposed device has the same or similar indications for use as the predicate with similar technological characteristics. The subject devices slightly differ in design, indications, and features from the predicate devices.

SUMMARY OF NON-CLINICAL TESTS:

The Steelco VS Steam Sterilizer non-clinical test was performed according to the standards in the following table. The testing demonstrated that the subject device met the acceptance criteria of these standards.

Test	Purpose of the Test	Acceptance Criteria	Result	Conclusion
Performance	To ensure that the performance, labeling, and safety requirements specified in AAMI ST8:2013 (ST8) are met.	Labeling complies with section 4.1 of ST8.	Compliance is documented in the labeling, user manual, service manual, and inventory of user interface screens and the ST8 Compliance Test Protocols for the individual models.	Pass
		Sterilizer design, construction, components, and accessories comply with section 4.2 of ST8.	Compliance is documented in the Machine Hardware Design Specification, risk analysis, FMEA section 3, mechanical aspects, ETL construction data file, ETL report IEC 61010-1 and 61010-2-040 compliance data report, ETL corrigendum, and the ST8 Compliance Test Protocols for the individual models.	Pass
		Sterilizer safety complies with section 4.3 of ST8.	Compliance is documented in the Machine Hardware Design Specification, risk analysis, FMEA section 3, mechanical aspects, ETL construction data file, ETL report IEC 61010-1 and 61010-2-040 compliance data report, and ETL corrigendum, and the ST8 Compliance Test Protocols for the individual models.	Pass
		Process monitoring and control devices comply with section 4.4 of ST8.	Compliance is documented in the Design Specification Control and User Interface Hardware, ETL construction data file, ETL report IEC 61010-1 and 61010-2-040 compliance data report, ETL corrigendum, and the ST8 Compliance Test Protocols for the individual models.	Pass
		Biological performance of sterilizers complies with section 4.5 of ST8.	Compliance is documented in the ST8 Compliance Test Protocols for the individual machines.	Pass
		Mechanical air removal complies with section 4.6 of ST8.	Compliance is documented in the ST8 Compliance Test Protocols for the individual machines.	Pass
		Moisture retention complies with section 4.7 of ST8.	Compliance is documented in the ST8 Compliance Test Protocols for the individual machines.	Pass

Test	Purpose of the Test	Acceptance Criteria	Result	Conclusion
General Electrical Safety	To ensure electrical safety in the construction and design of the sterilizers	Compliance with the appropriate provisions of IEC/UL 61010-1 and 61010-2-040	Compliance is documented in the ETL construction data file, ETL report IEC 61010-1 and 61010-2-040 compliance data report, and ETL corrigendum.	Pass
Sterilizer Electrical Safety	To ensure electrical safety in the construction and design of the sterilizers	Compliance with the appropriate provisions of IEC/UL 61010-1 and 61010-2-040	Compliance is documented in the ETL construction data file, ETL report IEC 61010-1 and 61010-2-040 compliance data report, and ETL corrigendum.	Pass
EMC testing	To ensure that the machine does not interfere with the operation of nearby machinery nor is interfered with by external EMC issues.	Compliance with the appropriate provisions of EN IEC 61326 part 1.	Compliance is documented in the EN IEC 61326 pt. 1 compliance report.	Pass
Software validation	To ensure that the software executes its designed functions and, if it fails, takes the machine to a safe state.	Compliance with software validation provisions of ISO 62304	Compliance is documented in the Software Requirements Specification Functional Specification Control and User Interface System, Risk Analysis, FMEA section 5 for control systems, and software validation	Pass
Pressure Vessel Safety	To ensure that the pressure vessels are designed and built in a safe manner.	Compliance with the safety requirements of ASME *Boiler and Pressure Vessel Code,* Section VIII (Division 1) for the chamber and jacket and Section 1 for the boiler (if furnished)	Meets requirements of ASME *Boiler and Pressure Vessel Code,* Section VIII (Division 1) for the chamber and jacket and Section 1 for the boiler (if furnished). See rating plate, section 6.2 of the ST8 Compliance Test Protocols for the individual machines	Pass

CONCLUSIONS:

The conclusions drawn from 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 K183410, Class II (21 CFR 880.6860), product code FLE.