September 18, 2024

LowTem Co., Ltd.
% Do Hyun Kim
CEO
BT Solutions, Inc.
Unit 904, Eonju-ro 86-gil 5, Gangnam-gu
Seoul 06210
Korea

Re: K231893
Trade/Device Name: LOWTEM Crystal 120
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: September 17, 2024
Received: September 17, 2024

Dear Do Hyun Kim:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher K. Dugard
-S

Christopher K. Dugard, M.S.
Assistant Director
THT4C1: Sterility Devices Team
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231893

Device Name
LOWTEM Crystal 120

Indications for Use *(Describe)*

The LOWTEM Crystal 120 Sterilizer System is indicated to sterilize pre-cleaned and dried reusable medical devices with nonabsorbable materials. The Crystal 120 sterilizer's Standard cycle can sterilize:

* Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors,
* Medical devices with single stainless-steel lumen with:

An inside diameter of 1mm or larger and a length of 125mm or shorter
An inside diameter of 2mm or larger and a length of 250mm or shorter
An inside diameter of 3mm or larger and a length of 400mm or shorter

※ The validation testing for this lumen size was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing.
- Contra-indication: It is contraindicated to sterilize single usable medical devices and devices made up with absorbable materials such as cellulose or wood.
- Intended user: trained nurse level or higher level of healthcare providers

The validated maximum load conditions

Total weight:
The validation performances were conducted using a validation load consisting of two instrument trays containing a total weight of 8.9kg(19.6lbs).
Usage of sterilization pouch:
The medical devices to be sterilized are packaged in Tyvek sterilization pouch and sealed. The pouched medical devices are placed at the trays.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"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

1 General Information

Applicant/Submitter:	LOWTEM CO., LTD.
Address:	100-2, Cheombok-ro, Dong-gu Daegu 41061, Korea
Contact Person:	Do Hyun Kim, BT Solutions, Inc.
Address:	Unit 904, Eonju-ro 86gil 5, Gangnam-gu, Seoul 06210, Korea. Tel: +82-2-538-9140 Email: ceo@btsolutions.co.kr

Preparation Date:	April 3, 2024

2 Device Name and Code

Device Trade Name:	LOWTEM Crystal 120
Common Name:	Low Temperature hydrogen peroxide sterilizer
Classification Name:	Sterilizer, Chemical
Product Code:	MLR
Regulation Number:	21 CFR 880.6860
Classification:	Class II
Review Panel:	General Hospital

Predicate Devices:

- Amsco® V-PRO™ 1 Low Temperature Sterilization System – K062297
- Amsco® V-PRO™ MAX Low Temperature Sterilization System – K102330

3. Device Description

The LOWTEM Crystal 120 low-temperature vaporized hydrogen peroxide sterilizer is a self-contained stand-alone device, using vaporized hydrogen peroxide as the sterilant.

The LOWTEM Crystal 120 includes the LCD touch monitor, Hydrogen Peroxide Supply (HPS) Unit, Sterilization Chamber Door, and Printer on the front of the Sterilizer.

4. Indications for Use / Intended Use

Intended Use:
The LOWTEM Crystal 120 Sterilizer System has a primary purpose to inactivate microorganisms on a broad range of medical devices and surgical instruments as a low temperature hydrogen peroxide sterilizer. Since the cycle operates within a dry environment and at low temperature, it is especially suitable for instruments sensitive to heat and moisture.

Indications for Use:

The LOWTEM Crystal 120 Sterilizer System is indicated to sterilize pre-cleaned and dried reusable medical devices with nonabsorbable materials. The Crystal 120 sterilizer's Standard cycle can sterilize:

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors,
- Medical devices with single stainless-steel lumen with:
  - ✓ An inside diameter of 1mm or larger and a length of 125mm or shorter
  - ✓ An inside diameter of 2mm or larger and a length of 250mm or shorter
  - ✓ An inside diameter of 3mm or larger and a length of 400mm or shorter

※ The validation testing for this lumen size was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing.
- Contra-indication: It is contraindicated to sterilize single usable medical devices and devices made up with absorbable materials such as cellulose or wood.
- Intended user: trained nurse level or higher level of healthcare providers

The validated maximum load conditions

Total weight:
The validation performances were conducted using a validation load consisting of two instrument trays containing a total weight of 8.9kg(19.6lbs).

Usage of sterilization pouch:
The medical devices to be sterilized are packaged in Tyvek sterilization pouch and sealed. The pouched medical devices are placed at the trays.

5. Technical Characteristics in Comparison to Predicate Devices

A technological comparison of the LOWTEM Crystal 120 sterilizer has been conducted to the legally marketed predicate devices:

	Predicate Device 1	Predicate Device 2	LOWTEM Crystal 120
510(K) Number	K062297	K102330	K231893
Manufacturer	STERIS Corporation	STERIS Corporation	LOWTEM CO., LTD.
Device Trade Name	Amsco® V-PRO™ 1 Low Temperature sterilization System	Amsco® V-PRO™ MAX Low Temperature sterilization System	LOWTEM Crystal 120
Classification	Sterilizer, Ethylene Oxide Gas	Sterilizer, Ethylene Oxide Gas	Sterilizer, Ethylene Oxide Gas
Indications for Use	The V-PRO 1 Low Temperature Sterilization System and Vaprox® HC Hydrogen Peroxide Sterilant (59%) are intended for use in terminal sterilization of cleaned, rinsed, and dried, reusable metal and nonmetal medical devices used in healthcare facilities. The V-PRO 1 Low Temperature Sterilization System 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: • an inside diameter of 1 mm or larger and a length of 125 mm or shorter • an inside diameter of 2 mm or larger and a length of 250 mm or shorter • an inside diameter of 3 mm or larger and a length of 400 mm or shorter * The validation testing for all lumen sizes was conducted using a	The Amsco® V-PROTM MAX 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 reusable 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. The Amsco V-PRO MAX Low Temperature Sterilization System's **Lumen** Cycle, cleared under K062297, can sterilize:' *Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors *Medical devices, including rigid endoscopes, with a single	The LOWTEM Crystal 120 Sterilizer System is indicated to sterilize pre-cleaned and dried reusable medical devices with nonabsorbable materials. The Crystal 120 sterilizer's **Standard cycle** can sterilize: * Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors, * Medical devices with single stainless-steel lumen with: • An inside diameter of 1mm or larger and a length of 125mm or shorter • An inside diameter of 2mm or larger and a length of 250mm or shorter • An inside diameter of 3mm or larger and a length of 400mm or shorter x The validation testing for this lumen size was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of

	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.	stainless steel lumen with: • an inside diameter of 1 mm or larger and a length of 125 mm or shorter • an insider diameter of 2 mm or larger and a length of 250 mmr or shorter • an inside diameter of 3 mm, or larger and a length of 400 mm or shorter * The validation testing for all lumen sizes was conducted using a maximum of twenty (20) iumens 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 Amsco V-PRO MAX Low Temperature Sterilization System's **Non-Lumen** Cycle, cleared under K083097, can sterilize: b Non-lumened instruments including non-lumened rigid endoscopes and non-lumened instruments with stainless steel 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 and two pouches for a total	lumens validated by this testing. - Contra-indication: It is contraindicated to sterilize single usable medical devices and devices made up with absorbable materials such as cellulose or wood. -Intended user: trained nurse level or higher level of healthcare providers The validated maximum load conditions Total weight: The validation performances were conducted using a validation load consisting of two instrument trays containing a total weight of 8.9kg (19.6lbs). Usage of sterilization pouch: The medical devices to be sterilized are packaged in Tyvek sterilization pouch and sealed. The pouched medical devices are placed at the trays.

		weight of 19.65 lbs. The Amsco V-PRO MAX Low Temperature Sterilization System's **Flexible** Cycle, the subject of this submission, 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 with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter, • or two lumens with: *one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter *and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter 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 with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter • or two lumens with: *one lumen having an inside diameter of 1 mm or larger and a length of 998 mum or shorter * and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter 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.	
Characteristics:			
Performance Claims	One Available Cycle • Lumen cycle	Three Available Cycles • Lumen cycle • non- lumen cycle • Flexible cycle	One Available Cycle • Standard cycle
Sterilant	VAPROX HC Sterilant. (59wt% hydrogen peroxide).	VAPROX HC Sterilant. (59wt% hydrogen peroxide).	Crystal SA-120 Sterilant. (59wt% hydrogen peroxide).

Software/Firmware control	PLC Cycle selection	PLC Cycle selection	Window embedded Controller factory

6. Performance Data

Performance characteristics of the subject device were tested using following consensus standards and end points:

Test Performed	Test objective	Acceptance criteria	Result
IEC 60601-1-2 Edition 4.0	General requirement for safety. Collateral standard Electromagnetic compatibility. Requirements and tests.	Pass / Fail	Pass
IEC 61010-1 Edition 3.1	Safety requirements for electrical equipment for measurement, control and laboratory use.	Pass / Fail	Pass
ISO 14971 Edition 3.0 Risk management	Identification of the risk and the activities of risk management.	Pass / Fail	Pass
IEC 62366-1 Edition 1.0 Usability Test	Application of usability engineering to medical devices	Pass / Fail	Pass
AOAC Sporicidal Activity Testing	Sterilant potency testing conducted per AOAC Official Method 966.04	Pass / Fail	Pass
D-value and total kill end point	Evaluation of the D- value examined and calculated and demonstration of >12 log reduction of *Geobacillus stearothermophilus* and its total kill endpoint tested in LOWTEM Crystal 120 sterilization system.	Pass / Fail	Pass
½ cycle modified total kill end point verification-worst case load	Evaluation of the validation loads under reduced injection weight to demonstrate a modified total end point.	Pass / Fail	Pass
Determination of worst-case material for VHP	Performance to determine the worst material (the most resistant) of 23 compatible materials of the LOWTEM Crystal 120 sterilizer.	Pass / Fail	Pass

½ cycle verification of mated surface	Evaluation of the sterility of the mated surfaces packaged in double pouch within the worst-case validation load in the LOWTEM Crystal 120 Standard ½ cycle.	Pass / Fail	Pass
½ cycle verification of mated surface	Evaluation of the sterility of the mated surfaces packaged in double pouch within the worst-case validation load in the LOWTEM Crystal 120 Standard ½ cycle.	Pass / Fail	Pass
½ cycle verification at multiple peroxide injection weight-worst lumen size	To determine the worst-case lumen size of the claimed lumens in the LOWTEM Crystal 120 Standard ½ cycle using reduced sterilant weights injected.	Pass / Fail	Pass
½ cycle verification of Lumen claims and worst-case materials	To verify the ability to sterilize in LOWTEM Crystal 120 Standard ½ cycle' worst-case lumen sizes (1.0mm x 125mm and 3.0mm x 400mm) and the worst- case material (neoprene) for surface sterilization in worst case validation loads.	Pass / Fail	Pass
½ cycle verification of worst-case material in double pouch	To verify the sterilization efficacy with the worst-case material (neoprene) packaged in double Tyvek pouch configuration in LOWTEM Crystal 120 Standard ½ cycle.	Pass / Fail	Pass
Evaluation of the system parameters	To confirm the sterilization efficacy using worst case validation load with worst case materials processed in the LOWTEM Crystal 120 Standard ½ cycle at the extremes of critical system parameters; chamber temperature, vaporizer temperature, hydrogen peroxide injection weight and pressure.	Pass / Fail	Pass

Final process qualification	To confirm the LOWTEM Crystal 120 Standard cycle performed in accordance with the sterilizer specification by inspecting the three lots of test accessories (SCBI, CI strip and CI tape) after sterilization cycle.	Pass / Fail	Pass
Simulated Use test	To verify the sterilization ability of representative worst- case devices processed in the LOWTEM Crystal 120 sterilization cycle.	Pass / Fail	Pass
Clinical In Use test	To demonstrate the ability of the LOWTEM Crystal 120 sterilizer to sterilize clinically soiled and cleaned medical devices.	Pass / Fail	Pass
Cytotoxicity Evaluation	To evaluate the compatible materials (23 materials) to determine the non-cytotoxicity of the materials extracts after processing in the LOWTEM Crystal 120 sterilizer.	Pass / Fail	Pass
Residual Evaluation	To evaluate the emission of hydrogen peroxide vapor in operator's breathing zone. The emitted level of hydrogen peroxide vapor was evaluated according to the OSHA hydrogen peroxide gas 8-hour Time Weighted Average (TWA) limit of 1ppm.	Pass / Fail	Pass

7. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K231893, the LOWTEM Crystal 120, is as safe, as effective, and performs as well as or better than the legally marketed predicate devices, cleared in K062297 and K102330.