October 6, 2020

Bolder Surgical, LLC
% Dave Yungvirt
Official Correspondent
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K202114
Trade/Device Name: CoolSeal Generator/CSL-200-50, CoolSeal Trinity (30 cm shaft)/CSL-TR105-30, CoolSeal Trinity (37 cm shaft)/CSL-TR105-37, CoolSeal Trinity (44 cm shaft)/CSL-TR105-44, CoolSeal Mini (20cm shaft)/CSL-MN103-20
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 5, 2020
Received: October 6, 2020

Dear Dave Yungvirt:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General 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)*
K202114

Device Name
CoolSeal Trinity, CoolSeal Mini, CoolSeal Generator

Indications for Use *(Describe)*

CoolSeal™ Trinity:
The CoolSeal™ Trinity is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The CoolSeal™ Trinity can be used on arteries up to and including 6 mm, veins, and vascular bundles up to and including 7 mm in diameter. It is indicated for use in general surgery procedures including urologic, vascular, and gynecologic.
The CoolSeal™ Trinity has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the CoolSeal™ Trinity for these procedures..

CoolSeal™ Mini:
The CoolSeal™ Mini is intended for use in open and laparoscopic general surgical procedures to seal blood vessels and vascular bundles up to and including 5 mm in diameter for use in adult and pediatric populations, wherever vessel ligation is required. The device is contraindicated for use in ENT procedures.

CoolSeal™ Generator:
The CoolSeal™ Generator is intended to provide Radio Frequency (RF) energy to compatible CoolSeal™ instruments for vessel-sealing applications. The specific application will depend on the compatible surgical device that is connected to the generator. This generator is designed to be used with only surgical devices compatible with the CoolSeal™ technology.

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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BOLDER SURGICAL

510(k) Summary

SUBMITTER

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Contact Person:
Nick Wong
Regulatory Affairs Manager

Date Prepared: September 25th, 2020

DEVICES

Trade Name / Model #:	CoolSeal™ Generator / CSL-200-50 CoolSeal™ Trinity • 30 cm / CSL-TR105-30 • 37 cm / CSL-TR105-37 • 44 cm / CSL-TR105-44 CoolSeal™ Mini • 20 cm / CSL-MN103-20
Common or Usual Name:	Bipolar Vessel Sealing System
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Class:	II
Produce Code:	GEI

PREDICATE DEVICES

Predicate Device for the CoolSeal™ Generator:
Trade Name: JustRight™ Generator
510(k): K160602

Predicate Device for the CoolSeal™ Trinity:
Trade Name: LigaSure™ Maryland jaw Sealer/Divider One-Step Sealing, Nano-Coated
510(k): K170869

Predicate Device for the CoolSeal™ Mini:
Trade Name: JustRight™ Sealer
510(k) K160602

REFERENCE DEVICE

Reference Device for the CoolSeal™ Trinity:
Trade Name: JustRight™ Sealer

510(k) K160602

DEVICE DESCRIPTION

CoolSeal™ Generator:
The CoolSeal™ Generator is a non-sterile, reusable device used outside the sterile field. The generator is designed to provide lower power bipolar Radio Frequency (RF) energy to CoolSeal™ vessel sealing devices for tissue-sealing applications.

CoolSeal™ Trinity:
The CoolSeal™ Trinity, a Maryland Laparoscopic Sealer, Divider, and Dissector, with a 5 mm diameter shaft is designed for use with the CoolSeal™ Generator or any generator with the CoolSeal™ technology. The Trinity is provided sterile and is a single-use disposable instrument. The Trinity creates seals by application of radiofrequency (RF) electrosurgical energy to vascular structures (vessels and lymphatics) or tissue bundles interposed between its jaws. A blade within the instrument is surgeon-actuated to divide tissue. The double action jaws have been designed to dissect tissue, which includes separating tissue planes and widening openings as necessary for the surgical procedure. The CoolSeal™ Trinity includes 3 different shaft lengths: 30 cm, 37 cm, and 44 cm.

CoolSeal™ Mini:
The CoolSeal™ Mini a Maryland Jaw Sealer, with a 3 mm diameter shaft is designed for use with the CoolSeal™ Generator or any generator with the CoolSeal™ technology. The Mini is provided sterile and is a single-use disposable instrument. The Mini creates seals by application of radiofrequency (RF) electrosurgical energy to vascular structures or tissue bundles interposed between its jaws. The double-action jaws have been designed to dissect tissue, which includes separating tissue planes and widening openings as necessary for the surgical procedure. The CoolSeal™ Mini is only available in one shaft length: 20 cm.

INDICATIONS FOR USE

CoolSeal™ Generator:
The CoolSeal™ Generator is intended to provide Radio Frequency (RF) energy to compatible CoolSeal™ instruments for vessel-sealing applications. The specific application will depend on the compatible surgical device that is connected to the generator. This generator is designed to be used with only surgical devices compatible with the CoolSeal™ technology.

CoolSeal™ Trinity:
The CoolSeal™ Trinity is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The CoolSeal™ Trinity can be used on arteries up to and including 6 mm, veins, and vascular bundles up to and including 7 mm in diameter.It is indicated for use in general surgery procedures including urologic, vascular, and gynecologic.

The CoolSeal™ Trinity has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the CoolSeal™ Trinity for these procedures.

CoolSeal™ Mini:

The CoolSeal™ Mini is intended for use in open and laparoscopic general surgical procedures to seal blood vessels and vascular bundles up to and including 5 mm in diameter for use in adult and pediatric populations, wherever vessel ligation is required.

The device is contraindicated for use in ENT procedures.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

This premarket notification contains three major components that make up the CoolSeal™ vessel sealing system. The predicates identified in this submission were identified for each major component to better demonstrate substantial equivalence with similar performing components. These are as follows (Subject Device/Predicate Device):

- The CoolSeal™ Generator / The JustRight™ Generator – both components are designed to provide lower power bipolar Radio Frequency (RF) energy to bipolar vessel sealing instruments for tissue-sealing applications. Both generators provide multiples signals (lights and tones) to users of the vessel sealing device related to the clinical function (e.g., seal complete, incomplete seal). The main difference between the subject device and the predicate device is the subject device has the ability to operate with multiple bipolar vessel sealing instruments. The subject device will automatically detect the compatible instrument and adjust the energy delivery algorithm accordingly. The predicate generator was only compatible with a single sealer.
- The CoolSeal™ Trinity / Ligasure™ Maryland jaw Sealer/Divider One-Step Sealing, Nano-Coated – both devices rely on the application of radio frequency (RF) energy to target tissue to create seals in the same sized structures (up to and including 7 mm in vasculature, tissue bundles, and lymphatics) interposed between the jaws of the instrument. At a high level, the subject device and predicate device is based on the following same technological elements:
    - Jaws – used to grasp, dissect, and manipulate tissue including sealing of intended structures.
    - Lever – used to open and close the jaws.
    - Activation button – allows the user to activate RF energy for sealing applications.
    - Cutting trigger – allows the user to divide (cut) sealed structures
    - Shaft – multiple shaft sizes available

  The following technological differences exist between the subject and predicate devices:
    - Bilateral jaws
    - Activation button is thumb activated vs lever activated
    - Lower power output level required for sealing of structures
- The CoolSeal™ Mini / JustRight™ Sealer – The CoolSeal™ Mini is the JustRight™ Sealer with some minor design modifications to enable its compatibility with the CoolSeal™ Generator. Excluding the following technological differences, the CoolSeal™ Mini is identical to the JustRight™ Sealer
    - Connector (plug) – the connector was swapped out from the predicate device to enable compatibility with the CoolSeal™ Generator
    - Aesthetics – non-patient contacting components were modified to reflect the new CoolSeal™ brand

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

CoolSeal™ Trinity:
The biocompatibility evaluation for the CoolSeal™ Trinity was conducted in accordance with ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," as recognized by FDA.

CoolSeal™ Mini:
The design changes made to the predicate device to create the CoolSeal™ Mini does not impact any of the patient contacting material. Therefore, the Biocompatibility testing previously submitted for the predicate device is still applicable to the CoolSeal™ Mini.

Electrical Safety and Electromagnetic Compatibility (EMC)

The CoolSeal™ system complies with relevant clauses of the ANSI/AAMI/ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-2:2017 standards for electrical safety and IEC 60601-1-2:2014 standard for EMC.

Mechanical and Functional Testing

Mechanical, electrical, and functional testing was carried out to verify that the proposed device performed as expected.

Ex-vivo and *In-vivo* Vessel Burst Pressure

CoolSeal™ Trinity:
Ex-vivo burst pressure testing of excised fresh porcine blood vessels was conducted on the subject device and predicate device to demonstrate equivalent bipolar electrosurgical vessel sealing performance. Additionally, *in-vivo* burst pressure testing of lymphatics was conducted on the subject device for comparison to the predicate to device to demonstrate equivalent bipolar electrosurgical vessel sealing performance.

CoolSeal™ Mini:
Ex-vivo burst pressure testing of excised fresh porcine blood vessels was conducted on the subject device and predicate device to demonstrate bipolar electrosurgical vessel sealing performance.

In-vivo Thermal Spread Comparison

CoolSeal™ Trinity:
Open laparotomy was performed in a porcine model using the subject device and predicate device. Each device was used to seal vessels and tissue bundles. Samples were excised for three-dimensional histological assessments (e.g., length, width, and depth) to quantify thermal spread in seals created by both devices. This study demonstrated that the subject device is as safe and effective as the predicate device.

Chronic Animal Study

CoolSeal™ Trinity:

A chronic study was conducted to assess safety and performance of bipolar vessel sealing with the subject device over the course of 28 days. All animals survived 28 days post-op without any complications. All vessel sealing effects on tissue maintained chronic hemostasis and healed as anticipated.

Clinical Studies

Clinical data was not necessary to support this premarket notification as the indications for use, device technology, and mechanism of action is not significantly different when compared to the predicate devices. Furthermore, nonclinical testing as described above is sufficient to establish substantial equivalence.

CONCLUSIONS

Based on a review of bench top assessments, comparison of the device classification, intended use, operating principles, technological characteristics, sterility, and biocompatibility, the subject devices are safe, as effective, and performs as well as the legally marketed predicate devices.