May 6, 2021

Bolder Surgical, LLC
Nicholas Wong
Regulatory Affairs Manager
331 S. 104th Street, Suite 200
Louisville, Colorado 80027

Re: K203183
Trade/Device Name: CoolSeal Trinity (30 cm shaft, 37 cm shaft, and 44 cm shaft)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 26, 2021
Received: March 29, 2021

Dear Nicholas Wong:

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)*
K203183

Device Name
CoolSeal Trinity

Indications for Use *(Describe)*
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. It is indicated for use in adult and pediatric populations (infants, children, and adolescents). 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. The device is contraindicated for use in ENT procedures.

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.

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510(k) Summary

SUBMITTER

Bolder Surgical, LLC.
331 S. 104th Street, Suite 200
Louisville, CO 80027

Phone: 720-287-7130
Fax: 720-287-7135

Contact Person:
Nick Wong
Regulatory Affairs Manager

Date Prepared: May 6th, 2021

DEVICES

Trade Name / Model #:	CoolSeal™ Trinity • 30 cm / CSL-TR105-30 • 37 cm / CSL-TR105-37 • 44 cm / CSL-TR105-44
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

Trade Name:	CoolSeal™ Trinity
510(k):	K202114

Trade Name:	JustRight™ Sealer
510(k)	K160602

DEVICE DESCRIPTION

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.

INDICATIONS FOR USE

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. It is indicated for use in adult and pediatric populations (infants, children, and adolescents). 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. The device is contraindicated for use in ENT procedures.

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Table 1 below presents the comparison of technological characteristics between the subject device and the two identified predicate devices.

Description	CoolSeal™ Trinity (Subject Device)	CoolSeal™ Trinity (Predicate/K202114)	JustRight™ Sealer (Predicate/K160602)
Indications for Use	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. It is indicated for use in adult and pediatric populations (infants, children, and adolescents). 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. The device is contraindicated for use in ENT procedures.	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.	The JustRight Surgical® Vessel Sealing System 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.
Where used (environment)	Operating Room		Operating Room
Intended User	Surgeons		Surgeons

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CoolSeal™ Trinity
Traditional 510(k) Submission
K203183

Description	CoolSeal™ Trinity (Subject Device)	CoolSeal™ Trinity (Predicate/K202114)	JustRight™ Sealer (Predicate/K160602)
Anatomical Sites	Vessels, tissue bundles, and lymphatics		Vessels, Tissue bundles
Anatomical Size	Arteries up to and including 6 mm, veins, and vascular bundles up to and including 7 mm in diameter		Up to and including 5 mm diameter
Patient Population	Adult and Pediatric (infants, children, and adolescents)	Not specified	Adult and Pediatric
Power Source	Bipolar energy platform		Bipolar energy platform
Primary Functions	Grasp, Dissect, Seal, Divide		Grasp, Dissect, Seal
Mechanism of Grasping	Hand actuated lever allows user to open or close		Hand actuated lever allows user to open or close
Mechanism of Dissection (Separation)	Bilateral jaw allows user to separate planes of tissue		Bilateral jaw allows user to separate planes of tissue
Mechanism of Action (Sealing)	Seal is created by application of RF energy to structures interposed between the jaws of the instrument.		Seal is created by application of RF energy to structures interposed between the jaws of the instrument.
Seal Activation	Button on the sealer instrument handle activated by thumb		Button on the sealer instrument handle activated by user
Knife Activation	Cutting trigger – non-energized		No cutting functionality.
Automatic sealing cycle	Yes		Yes
Rated Voltage (V_{peak})	190 V_{peak}		190 V_{peak}
Maximum Output Power	35 Watts		25 Watts
Jaw Dimensions – Side Width	Proximal Side Width: 4.5 mm Distal Side Width: 2.3 mm		Proximal Side Width: 3.3 mm Distal Side Width: 1.4 mm

BOLDER SURGICAL

CoolSeal™ Trinity
Traditional 510(k) Submission
K203183

Description	CoolSeal™ Trinity (Subject Device)	CoolSeal™ Trinity (Predicate/K202114)	JustRight™ Sealer (Predicate/K160602)
Thermal Coating on Jaws	Present		Present
Shaft Diameter	5 mm		3 mm
Shaft Length	30 cm, 37 cm, 44 cm		20 cm
Shaft Rotation	>360°		340°
Seal Length	19 mm		10.5 mm
Seal Quality	Greater than 3x systolic pressure		Greater than 3x systolic pressure
Seal Width/Plate	Seal Plate Width: 1.8 mm throughout		Seal Plate Width: Proximal: 3.3 mm Distal: 1.4 mm
Mean thermal spread	Less than 1 mm		Less than 1 mm
How Supplied	Sealer instruments are single use disposable		Sealer instruments are single use disposable
Tissue Contact Materials	Stainless steel, titanium, polymers, silicone, polymer adhesives, and insulating coatings		Stainless steel, titanium, polymers, silicone, polymer adhesives, and insulating coatings
Surgical Approach	Open or laparoscopic		Open or laparoscopic
Sterilization	Ethylene Oxide		Ethylene Oxide
Sterility Assurance Level	10^{-6}		10^{-6}

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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, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," as recognized by FDA.

Electrical Safety and Electromagnetic Compatibility (EMC)

The CoolSeal™ system complies with relevant clauses of the ANSI/AAMI/IEC 60601-1 and ANSI/AAMI/IEC 60601-2-2 standards for electrical safety and ANSI/AAMI/IEC 60601-1-2 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 to demonstrate effective bipolar electrosurgical vessel sealing performance. Additionally, *in-vivo* burst pressure testing of lymphatics was conducted on the subject device to demonstrate effective 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 Data

A literature review, including meta-analysis, was conducted to evaluate complication rates noted for vessel sealers in pediatric populations compared to adult populations. This information supports a device indication for use in both adult and pediatric populations.

CONCLUSIONS

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