November 15, 2023

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

Re: K231012
Trade/Device Name: CoolSeal Trinity
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 20, 2023
Received: October 24, 2023

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 (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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.11.15 13:42:02 -05'00'

Mark Trumbore, 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)*

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 vessels (arteries, 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). Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc. 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.

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

SUBMITTER

Bolder Surgical, LLC. (now part of Hologic, Inc.)
331 S. 104th Street, Suite 200
Louisville, CO 80027

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

Contact Person:
Nick Wong
Sr. Manager, Regulatory Affairs

Date Prepared: April 5th, 2023

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 DEVICE

Trade Name:	CoolSeal™ Trinity
510(k):	K211579

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 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 vessels (arteries, 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). Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc. 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Table 1 below compares technological characteristics between the subject and predicate devices. As Table 1 illustrates, all characteristics are the same, with the only difference being the identification of a new compatible electrosurgical generator.

Table 1. Presents the subject device compared to the predicate device.

Description	**CoolSeal™ Trinity (Subject Device)**	**CoolSeal™ Trinity (Predicate - K211579)**
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 vessels (arteries, 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). Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc. 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.	
Where used (environment)	Operating Room	
Intended User	Surgeons	
Anatomical Sites	Vessels, tissue bundles, and lymphatics	
Anatomical Size	Arteries, veins, and vascular bundles up to and including 7 mm in diameter	
Patient Population	Adult and pediatric populations (infants, children, and adolescents).	
Power Source	Bipolar energy platform	
Compatible Electrosurgical Generator	**CoolSeal Generator Da Vinci E-200**	**CoolSeal Generator**
Primary Functions	Grasp, Dissect, Seal, Divide	

Description	CoolSeal™ Trinity (Subject Device)	CoolSeal™ Trinity (Predicate - K211579)
Mechanism of Grasping	Hand actuated lever allows user to open or close	
Mechanism of Dissection (Separation)	Bilateral jaw allows the 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 Activation	Button on the sealer instrument handle activated by thumb	
Knife Activation	Cutting trigger – non-energized	
Automatic sealing cycle	Yes	
Rated Voltage (V_{peak})	190 V_{peak}	
Shaft Diameter	5 mm	
Shaft Length	30 cm, 37 cm, 44 cm	
Shaft Rotation	>360°	
Seal Length	19 mm	
How Supplied	Single-use disposable	
Tissue Contact Materials	Stainless steel, titanium, polymers, silicone, polymer adhesives, and insulating coatings	
Surgical Approach	Open or laparoscopic	
Sterilization	Ethylene Oxide	
Sterility Assurance Level	10^{-6}	

PERFORMANCE DATA

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

Electrical and Thermal Testing

Electrical and thermal testing verified that the proposed subject device performed as expected when connected to the E-200 generator.

Ex-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 that is equivalent to the predicate device.

CONCLUSIONS

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