May 6, 2021

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

Re: K203640
Trade/Device Name: CoolSeal Reveal
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 9, 2021
Received: April 12, 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)*
K203640

Device Name
CoolSeal Reveal

Indications for Use *(Describe)*
The CoolSeal™ Reveal is a bipolar electrosurgical instrument intended for use in open surgical procedures in adults and pediatrics where ligation and division of vessels, tissue bundles, and lymphatics is desired. The CoolSeal™ Reveal can be used on vessels (arteries and veins) up to and including 6 mm in diameter. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic, and reconstructive. Procedures may include but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis.
The CoolSeal™ Reveal is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, and parotidectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermallysensitive structures such as nerves and parathyroid glands.
The CoolSeal™ Reveal has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the CoolSeal™ Reveal for these 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

DEVICE

Trade Name / Model #:	CoolSeal™ Reveal / CSL-RV105-10
Common Name:	Bipolar Vessel Sealing System
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Class:	II
Produce Code:	GEI

PREDICATE DEVICES

Trade Name:	LigaSure Exact Dissector, Nano-Coated
510(k):	K173281
Common or Usual Name:	Bipolar Vessel Sealing System
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Class:	II
Produce Code:	GEI

Trade Name:	JustRight™ Sealer
510(k)	K160602
Common or Usual Name:	Bipolar Vessel Sealing System
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Class:	II
Produce Code:	GEI

DEVICE DESCRIPTION

CoolSeal™ Reveal:
The CoolSeal™ Reveal device is a sterile, single-use, hand-held bipolar vessel sealing device designed for use with the CoolSeal™ Generator. The CoolSeal™ Reveal is a hemostat-style

design with a 5 mm shaft diameter and 10 cm shaft length. The jaw is a curved Maryland-style jaw that rotates. The Reveal 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.

INDICATIONS FOR USE

CoolSeal™ Reveal:

The CoolSeal™ Reveal is a bipolar electrosurgical instrument intended for use in open surgical procedures in adults and pediatrics where ligation and division of vessels, tissue bundles, and lymphatics is desired. The CoolSeal™ Reveal can be used on vessels (arteries and veins) up to and including 6 mm in diameter. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic, and reconstructive. Procedures may include but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis.

The CoolSeal™ Reveal is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, and parotidectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands.

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Tables 1 and 2 below present the comparison of technological characteristics between the subject device and the two identified predicate devices.

Table 1. CoolSeal™ Reveal vs. LigaSure™ Exact

Description	CoolSeal™ Reveal (Subject Device)	LigaSure Exact (Primary Predicate)
Indications for Use	The CoolSeal™ Reveal is a bipolar electrosurgical instrument intended for use in open surgical procedures in adults and pediatrics where ligation and division of vessels, tissue bundles, and lymphatics is desired. The CoolSeal™ Reveal can be used on vessels (arteries and veins) up to and including 6 mm in diameter. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic, and reconstructive. Procedures may include but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis. The CoolSeal™ Reveal is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, and parotidectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands. The CoolSeal™ Reveal has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the CoolSeal™ Reveal for these procedures.	The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/ Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic, and reconstructive. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis. The instrument is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands. The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.
Where used (environment)	Operating Room	Operating Room
Intended User	Surgeon	Surgeon

Description	CoolSeal™ Reveal (Subject Device)	LigaSure Exact (Primary Predicate)
Anatomical Sites	Vessels, tissue bundles, and lymphatics	Vessels, tissue bundles, and lymphatics
Anatomical Size	Up to and including 6 mm diameter	Up to and including 7 mm diameter
Patient Population	Adult and Pediatric in General Surgery. Adult in ENT surgery.	Not specified (Adults assumed)
Power Source	Bipolar energy platform	Bipolar energy platform
Primary Functions	Grasp, Dissect, Seal, Divide	Grasp, Dissect, Seal, Divide
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	
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 is activated by user finger depression.	Button on the sealer instrument is hand activated by closing the handles until the button is depressed.
Knife Activation	Cutting trigger – non-energized	Cutting trigger – non-energized
Automatic sealing cycle	Yes	Yes
Rated Voltage (V_{peak})	190 V_{peak}	288 V_{peak}
Shaft Diameter	5 mm	N/A
Shaft Length	10 cm	N/A
Jaw Rotation	≤ 335°	N/A
Jaw Dimensions – Jaw Length and Side Width	Jaw Length: 12 mm Proximal Side Width: 4.3 mm Distal Side Width: 2.0 mm	Jaw Length: 20.6 mm Proximal Side Width: 4.2 mm Distal Side Width: 2.3 mm
Jaw Dimensions – Tip Width (proximal and distal)	Proximal: 5.2 mm Distal: 3.2 mm	Proximal: 6.7 mm Distal: 3.6 mm
Seal Plate Width	Seal Plate Width: 1.8 mm throughout	Seal Plate Width:

Description	CoolSeal™ Reveal (Subject Device)	LigaSure Exact (Primary Predicate)
		Proximal: 4.0 mm Distal: 1.75 mm
Maximum size structure (vessel, tissue bundles, lymphatic) for sealing	Up to 6 mm	Up to 7 mm
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	Open
Sterilization	Ethylene Oxide	Ethylene Oxide
Sterility Assurance Level	10^{-6}	10^{-6}

Table 2. CoolSeal™ Reveal vs. JustRight™ Sealer Comparison Table

Description	CoolSeal™ Reveal (Subject Device)	JustRight Sealer (Pediatric Predicate)
Indications for Use	The CoolSeal™ Reveal is a bipolar electrosurgical instrument intended for use in open surgical procedures in adults and pediatrics where ligation and division of vessels, tissue bundles, and lymphatics is desired. The CoolSeal™ Reveal can be used on vessels (arteries and veins) up to and including 6 mm in diameter. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic, and reconstructive. Procedures may include but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis. The CoolSeal™ Reveal is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, and parotidectomy) for ligation and division	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.

Description	CoolSeal™ Reveal (Subject Device)	JustRight Sealer (Pediatric Predicate)
	of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands. The CoolSeal™ Reveal has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the CoolSeal™ Reveal for these procedures.	
Where used (environment)	Operating Room	Operating Room
Intended User	Surgeon	Surgeon
Anatomical Sites	Vessels, tissue bundles, and lymphatics	Vessels, and tissue bundles
Anatomical Size	Up to and including 6 mm diameter	Up to and including 5 mm diameter
Patient Population	Adult and Pediatric in General Surgery. Adult in ENT surgery.	Adult and Pediatric in General Surgery.
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 is activated by user finger depression.	Button on the sealer instrument is activated by user finger depression.
Knife Activation	Cutting trigger – non-energized	No cutting functionality.

Description	CoolSeal™ Reveal (Subject Device)	JustRight Sealer (Pediatric Predicate)
Automatic sealing cycle	Yes	Yes
Rated Voltage (V_{peak})	190 V_{peak}	190 V_{peak}
Maximum Output Power	30 Watts	25 Watts
Shaft Diameter	5 mm	3 mm
Shaft Length	10 cm	20 cm
Jaw Rotation	≤ 335°	≤ 340°
Jaw Dimensions – Jaw Length and Side Width	Jaw Length: 12 mm Proximal Side Width: 4.3 mm Distal Side Width: 2.0 mm	Jaw Length: 10 mm Proximal Side Width: 3.3 mm Distal Side Width: 1.4 mm
Jaw Dimensions – Tip Width (proximal and distal)	Proximal: 5.2 mm Distal: 3.2 mm	Proximal: 3.3 mm Distal: 2.2 mm
Seal Plate Width	Seal Plate Width: 1.8 mm throughout	Seal Plate Width: Proximal: 3.3 mm Distal: 1.4 mm
Thermal Coating on Jaws	Present	Present
Maximum size structure (vessel, tissue bundles, lymphatic) for sealing	Up to 6 mm	Up to 5 mm
Tissue Contact Materials	Stainless steel, titanium, polymers, silicone, polymer adhesives, and insulating coatings	Stainless steel, titanium, polymers, silicone, polymer adhesives, and insulating coatings

Description	CoolSeal™ Reveal (Subject Device)	JustRight Sealer (Pediatric Predicate)
Surgical Approach	Open	Open and Laparoscopic
Sterilization	Ethylene Oxide	Ethylene Oxide
Sterility Assurance Level	10^{-6}	10^{-6}

PERFORMANCE DATA

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

Biocompatibility Testing

The biocompatibility evaluation for the CoolSeal™ Reveal 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™ Reveal 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

Ex-vivo burst pressure testing of excised fresh porcine blood vessels was conducted on the subject device and primary predicate to demonstrate effective bipolar electrosurgical vessel sealing performance. Additionally, *in-vivo* burst pressure testing of lymphatics was conducted on the subject device and primary predicate to demonstrate effective bipolar electrosurgical vessel sealing performance.

In-vivo Thermal Spread Comparison

Open laparotomy was performed in porcine and ovine animal models using the subject device and primary 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

A chronic study was conducted to assess the safety and performance of bipolar vessel sealing with the subject device over the course of 23 days. All animals survived 23 days post-op without any complications. All vessel sealing effects on tissue maintained chronic hemostasis and healed as anticipated.

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.