June 17, 2026

Hologic, Inc.
Brynn Dietzel
Sr. Regulatory Affairs Specialist
250 Campus Dr.
Marlborough, Massachusetts 01752

Re: K253634
Trade/Device Name: CoolSeal Generator® (CSL-200-90)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 15, 2026
Received: June 15, 2026

Dear Brynn Dietzel:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2026.06.17 18:08:34 -04'00'

For
Colin Kejing Chen, Ph.D.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253634

Please provide the device trade name(s).

CoolSeal Generator® (CSL-200-90)

Please provide your Indications for Use below.

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 only with surgical devices compatible with the CoolSeal technology.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Traditional 510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807.92.

Date Prepared: November 18, 2025

Manufacturer:
Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA

Establishment Registration #: 1222780

Primary Contact Person:
Brynn Dietzel
Sr. Regulatory Affairs Specialist
P: 267.885.5470

Secondary Contact Person:
Nick Wong
Director, Regulatory Affairs
P: 720-750-6092

Identification of the Device:

Proprietary/Trade Name:	CoolSeal® Generator
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Number:	21 CFR 878.4400
Product Code:	GEI (Electrosurgical cutting and coagulation device and accessories)
Device Class:	Class II
Review Panel:	General & Plastic Surgery

Identification of the Legally Marketed Predicate Device:

Trade Name:	CoolSeal® Generator
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Number:	21 CFR 878.4400
Product Codes:	GEI (Electrosurgical cutting and coagulation device and accessories)
Device Class:	Class II
Review Panel:	General & Plastic Surgery
Submitter/510(k) Holder:	Bolder Surgical, LLC (subsidiary of Hologic, Inc.)
Clearance:	K202114 (October 6, 2020)

The legally marketed predicate device, the CoolSeal Generator (K202114) has not been subject to design-related recalls.

Device Description:
The CoolSeal Generator is a non-sterile, reusable device used outside the sterile field. The generator is designed to provide low power bipolar Radio Frequency (RF) energy to CoolSeal vessel sealing devices for tissue-sealing applications. The energy platform automatically detects CoolSeal coded instruments and adjusts the energy delivery algorithm accordingly. The CoolSeal Generator also provides multiple signals (lights and tones) to users of the vessel sealing device related to clinical function (e.g. seal complete, incomplete seal). The low power system has a maximum output voltage of 110 Vrms (peak voltage: 190V) and a maximum output current of 2.5 Amps. The maximum output power of the low power system is 90 Watts.

Indication for Use:
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 only with surgical devices compatible with the CoolSeal technology.

Comparison with Predicate Device:
The proposed CoolSeal Generator has the same intended use, method of operation, and key functional elements as the predicate device, the CoolSeal Generator (K202114). The proposed device presents similar technological characteristics as the predicate device in order to Radio Frequency (RF) energy to compatible CoolSeal instruments for vessel sealing applications. The subject device, the proposed generator, incorporates an incremental change to the predicate device to provide the capability of increased power output. The specific changes that support the capability for increased power output include an update to the software algorithm and incorporation of new Printed Circuit Board Assembly (PCBA) components. This change does not result in any change to the specified power outputs associated with currently commercialized devices.

Substantial Equivalence:
The subject device has the same intended use, method of operation, and key functional elements as the predicate device, the CoolSeal Generator (K202114). The subject device presents similar technological characteristics as the predicate device in order to provide radiofrequency (RF) energy to compatible CoolSeal instruments for vessel sealing applications.

The minor technological differences between the proposed and predicate device do not raise new questions of safety or effectiveness and are supported by performance data. Based on the information submitted in this premarket notification, the next generation of the CoolSeal Generator has been shown to be substantially equivalent to the predicate device (K202114).

Summary of Testing:
The CoolSeal Generator (CSL-200-90) has successfully passed the following performance testing to demonstrate that the device is substantially equivalent to the predicate device and meets design specifications.

Electrical Safety and Electromagnetic Compatibility Testing

The CoolSeal Generator underwent electrical safety and electromagnetic compatibility testing in accordance with the following standards:

- IEC 60601-1:2005+A1:2012 + A2:2020 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014+A1:2020 – Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
- IEC 60601-2-2: 2017+A1:2023 – Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Performance Testing

The following performance testing was conducted to support the substantial equivalence of the CoolSeal Generator to the predicate:

- Energy and Power Output Bench Testing
- Impedance Measurement Bench Testing
- Software Unit, Integration, and System Testing
- Applied Part Compatibility Bench Testing

Conclusion:

Based on the information submitted in this premarket notification, including the intended use, technological characteristics, and operational use, the subject device has been shown to be substantially equivalent to the predicate device, the CoolSeal Generator (K202114).