April 10, 2026

Ascblue Corporation
Helen Xie
Quality Assurance Manager
480 Apollo St.
Suite D
Brea, California 92821

Re: K253777
Trade/Device Name: Ascblue (8010)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 25, 2025
Received: November 28, 2025

Dear Helen Xie:

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: 2026.04.10 10:17:54 -04'00'

For
Colin Kejinng 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.	K253777

Please provide the device trade name(s).

Ascblue 8010

Please provide your Indications for Use below.

The Electrosurgical Generator 8010 is indicated for cutting and coagulation of tissue in general surgery procedures via monopolar and bipolar modes. It is intended for use with monopolar handpieces and dispersive electrodes, or with bipolar handpieces and footswitches.

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

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

510(k) #: K253777

510(k) Summary

Prepared on: 2026-03-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ascblue Corporation
Applicant Address	480 Apollo St. Ste D. Brea CA 92821 United States
Applicant Contact Telephone	6266785725
Applicant Contact	Mr. Yuexin Guo
Applicant Contact Email	service@ascblue.com
Correspondent Name	Ascblue Corporation
Correspondent Address	480 Apollo St. Ste D. Brea CA 92821 United States
Correspondent Contact Telephone	6266786216
Correspondent Contact	Mrs. Helen Xie
Correspondent Contact Email	qa@ascblue.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Ascblue (8010)
Common Name	Electrosurgical cutting and coagulation device and accessories
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number	878.4400
Product Code(s)	GEI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201224	8070 Electrosurgical Generator	GEI

Device Description Summary

21 CFR 807.92(a)(4)

The subject device of this submission is the Ascblue 8010 Electrosurgical Generator.
Medrange MB8010 and Surnic 8010 are commercial branding names under which the same device platform may be marketed.
All testing, validation, and documentation provided in this submission apply to the Ascblue 8010 device platform.

The Electrosurgical Generator 8010 is indicated for use in general electrosurgical procedures for monopolar cutting, monopolar coagulation, and bipolar coagulation of tissue. It is intended to be used with monopolar handpieces and dispersive electrodes, or with bipolar handpieces and footswitches.

Electrosurgery is the application of high-frequency (radio-frequency, RF) alternating current to biological tissue in order to cut, coagulate, desiccate, or fulgurate tissue. The RF current produces heating of the tissue through intracellular oscillation of ionized molecules, which leads to an elevation of intracellular temperature.

The benefits of electrosurgery include the ability to perform precise surgical cutting with effective hemostasis and limited blood loss. Electrosurgical devices are widely used in both inpatient operating rooms and outpatient surgical procedures to facilitate tissue

dissection and minimize intraoperative bleeding.
The device is an advanced microprocessor-controlled electrosurgical generator providing: 4 Monopolar cutting modes / 4 Monopolar coagulation modes / 4 Bipolar modes, and Return Safety Monitor (RSM) for dispersive electrode quality check.

The device includes an internal USB port that is physically present on the hardware.
This USB port is intended solely for manufacturing, service, and testing purposes.
The port is sealed prior to distribution and is not user-accessible, not visible, and not intended for clinical use in the marketed configuration.
The device does not support user-accessible data transfer, networking, or external communication functions.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Electrosurgical Generator 8010 is indicated for cutting and coagulation of tissue in general surgery procedures via monopolar and bipolar modes. It is intended for use with monopolar handpieces and dispersive electrodes, or with bipolar handpieces and footswitches.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for Use
The indications for use of the subject device (8010) are the same as those of the predicate device (8070). Both devices are intended for monopolar and bipolar electrosurgery for cutting and coagulation. Differences in descriptive wording do not constitute a new intended use.

Technological Characteristics
The 8010 and the predicate 8070 share the same principle of operation, energy source, and functional modes (monopolar cut, monopolar coagulation, and bipolar). Differences in maximum output power, voltage, crest factor, and operating frequency are within acceptable ranges defined by IEC 60601-2-2 and do not raise new questions of safety or effectiveness.

Conclusion
Based on the comparison, the 8010 is substantially equivalent to the predicate device 8070 in intended use and technological characteristics.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device 8010 and the predicate device 8070 share the same intended use: monopolar and bipolar electrosurgery for cutting and coagulation. Both devices use the same energy source and employ similar operating modes (monopolar cut, monopolar coagulation, and bipolar).

The technological characteristics are comparable. The maximum output powers (e.g., 300 W vs. 320 W for monopolar cut, 120 W vs. 100 W for monopolar coagulation, and 90 W vs. 240 W for bipolar) fall within the normal performance range of electrosurgical generators. Differences in output voltage, crest factor, and operating frequency remain within the IEC 60601-2-2 standard and do not introduce new risks.

Other features, including waveforms (sinusoidal constant/modulated), controls (hand and foot), and power supply, are the same. Both devices have nearly identical dimensions and weight, and differences in display type (LED vs. LCD) do not affect functionality.

Conclusion: The 8010 has the same intended use and similar technological characteristics as the 8070. The observed differences do not raise new questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Bench testing was performed to evaluate the safety and performance of the 8010 Electrosurgical Generator in accordance with FDA's "Electrosurgical Devices for General Surgery" Guidance (March 9, 2020). Testing included:
• ESU Output Performance: Waveform analysis and power output curves across 100–2000 Ω loads for all monopolar and bipolar modes, compared with predicate device.
• Mechanical and Electrical Safety of Accessories: Mechanical strength, insulation integrity, and durability testing of active electrodes and handpieces; functional and durability testing of the footswitch.
• Neutral Electrode Testing: Thermal performance, contact impedance, and adhesion testing per IEC 60601-2-2.
• System-Level Testing: Ex vivo tissue studies measuring thermal spread and coagulation effects; verification of contact quality monitoring (CQM) and safety features.
Bench testing demonstrated that the 8010 Electrosurgical Generator is as safe and effective as the predicate electrosurgical generators. The device performed as intended, meeting all applicable requirements for output accuracy, safety, and EMC, with no unexpected risks identified, and is substantially equivalent to the predicate device, in accordance with FDA's "Electrosurgical Devices for General Surgery"

Guidance (March 9, 2020) and IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2 standards.

Bench testing demonstrated that the 8010 Electrosurgical Generator is as safe and effective as the predicate electrosurgical generators. The device performed as intended, meeting all applicable requirements for output accuracy, safety, and EMC, with no unexpected risks identified.