September 23, 2025

Olympus Winter & Ibe GmbH
℅ Teffany Hutto
Mgr., Program Regulatory Affairs RA/QA
Olympus Surgical Technologies America
Gyrus ACMI, Inc.
800 West Park Drive
Westborough, Massachusetts 01581

Re: K252043
Trade/Device Name: Bipolar applicator CelonProBreath (WB990310); Bipolar applicator CelonProSleep plus (WB990311); Bipolar applicator CelonProBreath (WB990210); Bipolar applicator CelonProSleep plus (WB990211)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 30, 2025
Received: June 30, 2025

Dear Teffany Hutto:

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.

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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.	K252043

Please provide the device trade name(s).

Bipolar applicator CelonProBreath (WB990310);
Bipolar applicator CelonProSleep plus (WB990311);
Bipolar applicator CelonProBreath (WB990210);
Bipolar applicator CelonProSleep plus (WB990211)

Please provide your Indications for Use below.

Bipolar applicator CelonProBreath is intended for use with a compatible electrosurgical generator. This method of treatment is also called bipolar Radiofrequency Induced Thermotherapy (RFITT).

Bipolar applicator CelonProBreath is indicated for ablation and coagulation of soft tissue in otorhinolaryngeal surgery, specifically:
– Shrinkage of submucosal tissue in nasal airway obstruction by reduction of hypertrophic nasal turbinates.
The product is intended to be used for patients from 2 years and up.

Bipolar applicator CelonProSleep plus is intended for use with a compatible electrosurgical generator. This method of treatment is also called bipolar radiofrequency induced thermotherapy (RFITT).

Bipolar applicator CelonProSleep plus is indicated for ablation and coagulation of soft tissue in otorhinolaryngeal surgery, specifically:
- Shrinkage of submucosal tissue and tissue coagulation in the soft palate for the treatment of snoring.
The product is intended to be used for patients from 18 years up.

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) Summary K252043

for

Bipolar applicator CelonProBreath (WB990210 and WB990310) and bipolar applicator CelonProSleep plus (WB990211 and WB990311)

1 General Information

Applicant:	Olympus Winter & Ibe GmbH Kuehnstrasse 61 22045 Hamburg Germany Establishment Registration Number: 9610773
Official Correspondent:	Teffany Hutto PROGRAM MGR. REGULATORY AFFAIRS RA/QA Olympus Surgical Technologies America Gyrus ACMI, Inc. 800 West Park Drive Westborough, MA 01581 Phone: 512-508-6550 Email: teffany.hutto@olympus.com Establishment Registration No.: 3003790304
Manufacturing site:	Olympus Medical Products Czech Ul Telickova 457/29 Prerov II Predmosti, CZ 75124 Establishment Registration No.: 3007960282
Date Prepared:	September 9, 2025

2 Device Identification

Device name and models:	Bipolar applicator CelonProBreath Bipolar applicator CelonProSleep plus
Model numbers:	Bipolar applicator CelonProBreath: WB990210, WB990310 Bipolar applicator CelonProSleep plus: WB99211, WB990311
Regulation Number; Name:	21 CFR 878.4400; Electrosurgical cutting and coagulation device and accessories.
Device Classification name:	Electrosurgical, Cutting & Coagulation & Accessories
Product code:	GEI
Device Class:	Class II
Review Panel:	General & Plastic Surgery

3 Predicate Device

The bipolar applicator CelonProBreath (WB990210 and WB990310) is considered substantially equivalent to the legally marketed device CelonProBreath (WB990210) and bipolar applicator CelonProSleep plus (WB990211 and WB990311) is considered substantially equivalent to the legally marketed device CelonProSleep plus (WB990211). Please refer to **Table 1** for further details on the predicate devices.

Table 1: Identification of predicate device

Predicate Device	Article Number	Manufacturer	510(k) Number
CelonProBreath	WB990210	Olympus Winter & Ibe GmbH	K032838
CelonProSleep PLUS	WB990211	Olympus Winter & Ibe GmbH	K032838

4 Product Description

The devices subject to this submission are sterile, single-use devices: the bipolar applicator CelonProBreath (WB990210 and WB990310) and the bipolar applicator CelonProSleep plus (WB990211 and WB990311). The devices are for use with a compatible electrosurgical generator. This method of treatment is also called bipolar radiofrequency induced thermotherapy (RFITT). The devices are intended for the ablation and coagulation of soft tissue in otorhinolaryngeal surgery.

Bipolar applicator CelonProBreath (WB990210 and WB990310) is specifically used for shrinkage of submucosal tissue in nasal airway obstruction by reduction of hypertrophic nasal turbinates.

Bipolar applicator CelonProSleep plus (WB990211 and WB990311) is specifically used for shrinkage of submucosal tissue and tissue coagulation in the soft palate for the treatment of snoring.

5 Indications for Use

Bipolar applicator CelonProBreath is intended for use with a compatible electrosurgical generator. This method of treatment is also called bipolar Radiofrequency Induced Thermotherapy (RFITT).

Bipolar applicator CelonProBreath is indicated for ablation and coagulation of soft tissue in otorhinolaryngeal surgery, specifically:
- Shrinkage of submucosal tissue in nasal airway obstruction by reduction of hypertrophic nasal turbinates.
The product is intended to be used for patients from 2 years and up.

Bipolar applicator CelonProSleep plus is intended for use with a compatible electrosurgical generator. This method of treatment is also called bipolar radiofrequency induced thermotherapy (RFITT).

Bipolar applicator CelonProSleep plus is indicated for ablation and coagulation of soft tissue in otorhinolaryngeal surgery, specifically:
- Shrinkage of submucosal tissue and tissue coagulation in the soft palate for the treatment of snoring.
The product is intended to be used for patients from 18 years up.

Changes to Indications for Use:
The Indications for Use were changed from general to specific in order to define the target patient group more clearly. For CelonProBreath, scientific literature including a total of 174 pediatric patients treated for nasal airway obstruction by reduction of hypertrophic nasal turbinates was provided. In the first article (n = 93), subjects were distributed across the following age groups: 2–3 years: 9 patients, 4–9 years: 84 patients. In the second article (n = 81), patients ranged from 4 to 15 years (mean 10.3 ± 2.5 years). For a related device (n = 86), subjects were between 1–17 years of age, including 5 patients younger than 3 years, with a mean age of 9.4 ± 4.4 years. Reported complications were limited to mild, transient events such as mild bleeding, crusting, infection, pain, or short-term edema.
For CelonProSleep plus, three scientific articles regarding the use for shrinkage of submucosal tissue and tissue coagulation in the soft palate for the treatment of snoring in the target population were provided, two with the CelonProSleep plus devices including patients between 20–65 years. And one article without specified device for patients <21 years. No major complications were noted. Additionally, an anatomical evaluation in patients aged 18–22 years demonstrated that palatal growth is complete in female patients by age 15. In male participants, there may be palatal growth at older ages, whereas the main growth occurs between 12–15 years.
Additionally, slight changes to the wording of the Indications for Use were made compared to the predicate device to improve clarity. These differences do not affect the safety or effectiveness of the device when used as labeled.

6 Technological Characteristics

The technological characteristics of the subject devices are considered equivalent to the predicate device.

The subject devices and predicate device share the following characteristics:

- Bending angle
- Diameter of active length
- Max. shaft diameter
- Active length
- Cable length
- Maximum permitted RF power output
- Gamma sterilization
- Sterile barrier system: Tyvek-film pouch

The following changes to the subject device are introduced:

- The subject devices bipolar applicator CelonProBreath (WB990310) and bipolar applicator CelonProSleep plus (WB990311) contain a 2-pin plug to be compatible with CELON ELITE ESG-200 generator, which supports multiple modes. The subject devices bipolar applicator CelonProBreath (WB990210) and bipolar applicator CelonProSleep plus (WB990211) that are also the predicate devices are connected to the LabENT generator with a 3-pin plug, which only supports one mode.
- The subject devices bipolar applicator CelonProBreath (WB990310) and bipolar applicator CelonProSleep plus (WB990311) contain a RFID tag, which allows only usage of a subset of bipolar coagulation modes of ESG-200 generator.
- The material of the sheath tube/ additional insulation and tubing was changed to a material from the same material group.
- Re-calculation of the upper gamma dose for the low-density worst case acc. to latest recognized version of ISO 11137 (ISO/TS 11137- 4:2020-06): 42 kGy instead of 40 kGy.
- The Instructions for Use were updated according to the latest template and the company design and chapter "Patient target group" was added as follows:
    - bipolar applicator Celon ProSleep plus (WB99211, WB9903100): "The product is intended to be used for patients from 18 years up."
    - bipolar applicator CelonProBreath (WB990210, WB990310): "The product is intended to be used for patients from 2 years and up."

As stated above, the subject and predicate devices have similar design characteristics and show comparable performance. As demonstrated in the non-clinical testing, the different technological characteristics do not negatively alter the safety and effectiveness of the subject device.

7 Non-clinical and/or clinical test summary and conclusions

Non-clinical performance tests were carried out to ensure that the subject devices function as intended and meet design specifications. All standards applied are FDA recognized international standards.

All data was prepared in accordance with the FDA guidance, “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery” Guidance for Industry and Food

and Drug Administration Staff, issued on March 9, 2020. The guidance was followed for all relevant sections.

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

7.1 Biocompatibility testing

Biocompatibility tests according to ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11 have been successfully performed.

7.2 Electrical Safety and Thermal Safety

The bipolar applicator CelonProBreath (WB990210 and WB990310) and the bipolar applicator CelonProSleep plus (WB990211 and WB990311) have been successfully tested for electrical and thermal safety in accordance with IEC 60601-1 and IEC 60601-2-2.
To outline that these performance characteristics have been met the submission contains the respective validations, tests and an outline of the design as required by the recognized standard IEC 60601-2-2, *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* (recognition number: 6-389) assigned to the product code GEI.

7.3 Electromagnetic compatibility (EMC)

The electromagnetic compatibility testing was carried out in accordance with IEC 60601-1-2.
The FDA guidance, Electromagnetic Compatibility (EMC) of Medical Devices, Guidance for Industry and Food and Drug Administration Staff, issued June 6, 2022, has been followed.

7.4 Reprocessing, Sterilization and Shelf Life

The bipolar applicator CelonProBreath (WB990210 and WB990310) and bipolar applicator CelonProSleep (WB990211 and WB990311) are sterile single use devices with a shelf life of 39 months.
ISO 11137-1 and ISO 11137-2 are used for validation of the sterilization method.

7.5 Performance testing - Bench

The bench testing was carried out in accordance with the FDA guidance “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery” Guidance for Industry and Food and Drug Administration Staff, issued on March 9, 2020.

Testing of equivalence was performed in comparison to the predicate devices in relevant aspects associated with tissue effects and thermal effects.
These comprehensive bench tests support equivalence to the predicate devices. Testing confirmed that comparable tissue effects could be achieved for applicable power settings with applicable tissue types.

7.6 Risk management

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2019.

A usability process was followed in accordance with IEC 62366-1:2015 + COR1:2016 + A1:2020, Annex C and IEC 60601-1-6:2010 +A1:2013+A2:2020 taking into account the FDA Guidance Document ”Applying Human Factors and Usability Engineering to Medical Devices” (February 3, 2016), and FDA Draft Guidance Document" Content of Human Factors Information in Medical Device Marketing Submissions” (December 9, 2022).

7.7 Performance testing – Clinical

No clinical study was performed to demonstrate substantial equivalence.

8 Conclusion

The performance data support the safety of the devices and demonstrate that the subject devices comply with the recognized standards as specified.

Based on the intended use, technological characteristics, performance data, and nonclinical tests performed, the subject devices: bipolar applicator CelonProBreath (WB990210 and WB990310) and bipolar applicator CelonProSleep plus (WB990211 and WB990311), are substantially equivalent to the legally marketed predicate devices: CelonProBreath (WB990210) and CelonProSleep PLUS (WB990211). The subject devices are as safe and as effective as the predicate devices, and perform as well as the legally marked devices cleared under K032838.