March 24, 2020

Medtronic Navigation
Gina Cunsolo
Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K193579
Trade/Device Name: PlasmaBlade X 3.0S LIGHT
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 20, 2019
Received: December 23, 2019

Dear Gina Cunsolo:

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)*
K193579

Device Name
PlasmaBlade X 3.0S LIGHT

Indications for Use *(Describe)*
The Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological 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.

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## 510(k) Summary

**Submitter:** Medtronic Navigation
826 Coal Creek Circle
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**Contact Person:** Gina Cunsolo
Regulatory Affairs Specialist
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**Date Summary Prepared:** March 19, 2020

**Device Trade Name:** PlasmaBlade X 3.0S LIGHT

**Common Name:** Electrosurgical Instrument

**Classification Name:** Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)

**Product Code:** GEI

**Predicate Devices:** PlasmaBlade X 3.0S (K181257)
PlasmaBlade 3.0S (K093695)

**Reference Device:** PhotonBlade (K162053)

**Device Description:** The PlasmaBlade™ X 3.0S LIGHT is a single-use, monopolar RF device. It is designed to be used with the qualified Generator as part of the Surgery System. It can be operated with the integrated hand switch or a qualified Footswitch. The PlasmaBlade™ X 3.0S LIGHT consists of a single bendable blade and telescoping shaft that can be configured in both standard and extended length. The finger grip also incorporates a suction lumen for the evacuation of smoke and fluids. The device also has integrated LED-based illumination.

**Indications for Use:** The Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological procedures.

**Substantial Equivalence Comparison**

Two predicate devices (cleared by Medtronic Advanced Energy) were used for substantial equivalence comparison to the subject device.

| Attribute | PlasmaBlade X 3.0S LIGHT (Subject – K193579) | PlasmaBlade X 3.0S (K181257) | PlasmaBlade 3.0S (K093695) |
|---|---|---|---|
| **Intended Use/Indications for Use** | The Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological procedures. | Same | Same |
| **Mechanism of action/principle od operation** | RF Monopolar Energy | Same | Same |
| **Power Output** | **Max power:** 50W +/- 20% 9Cut 8, Cut 10 and Coag 10)<br><br>**Min power**: ~0.5W +/- 1W at (Cut 1) | Same | Same |
| **Sterilization** | EtO | Same | Same |
| **Biocomp** | External communicating device <24 hours, tested to ISO 10993-1 | Same | Same |
| **Blade Material** | Coated Stainless Steel | Same | Same |
| **Integrated Suction** | Yes | Same | Same |
| **LED Light** | Yes | No | No |

**Technological Characteristics:**

The predicate PlasmaBlade devices and subject PlasmaBlade X 3.0S LIGHT device are intended for RF-based cutting and coagulation. The PlasmaBlade X 3.0S LIGHT device shares the same operational characteristics as the predicate platforms, comprised of a radio-frequency generator which supplies RF power to disposable electrode devices for electrosurgical procedures. The differences between the subject and predicate devices are:

- The PlasmaBlade X 3.0S LIGHT contains an LED light source located at the blade end of the handpiece. Bench testing was completed in order to ensure all light specifications were met.
- An updated blade geometry to the subject device Bench testing was completed to ensure the new geometry did not affect performance of the blade.
- Updated blade coating to incorporate material utilized in the previous generation of the PlasmaBlade 3.0S device (K093695).

Similar to other devices in the field (i.e. PhotonBlade K162053), the PlasmaBlade X 3.0S LIGHT contains an LED-light source to assist in illuminating the field.

**Summary of Non-Clinical Testing:**

The design and performance of the new features of the PlasmaBlade X 3.0S LIGHT were verified and validated through bench testing. Medtronic product development processes and the finalized FDA Guidance Document, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff," issued on August 15, 2016, were utilized to determine applicable bench testing requirements.

Sterilization, Biocompatibility, IEC and EMC Testing were conducted in compliance with the following FDA recognized consensus standards:

| Standard | Title |
|---|---|
| ISO 11135 2nd Ed 2014 | Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices |
| 10993-5 Third Edition 2009-06-01 | Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity |

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| 10993-10 Third Edition 2010-08-01 | Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization |
| 10993-11 Third Edition 2017-09 | Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity |
| ES60601-1:2005/(R)2012 And A1:2012, | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) |
| 60601-2-2 Edition 6.0 2017-03 | 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 |
| 60601-1-2 Edition 4.0 2014-02 | Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests |

Bench Testing

| Test | Description |
|---|---|
| Design Verification | Design Verification was completed to guarantee all new design features functioned appropriately. |

In comparison to the predicate devices, the subject PlasmaBlade X 3.0S LIGHT device was evaluated via bench testing to ensure all features performed in an equivalent manner to the predicates. Bench testing included consideration of the geometry change as well as the addition of the blade coating. All design features were met. In addition, the subject device was tested for multiple light performance specifications, which included allowable activation amounts, lux ranges (minimum and maximum), and light diameter at extension and collapse. All light specifications were met.

Animal Testing

| Test | Description |
|---|---|
| Tissue Testing | Thermal damage testing was completed on muscle, skin, and liver in accordance with the guidance entitled, “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery,” issued August 2016, to ensure substantial equivalence to predicate. |

| | |
|---|---|
| | Similar to the predicate devices, thermal damage testing was completed on a porcine model to ensure the subject device was substantially equivalent to the predicates. The muscle tissue testing was completed in-vivo, while the skin and liver tissue testing was completed ex-vivo. Testing concluded the subject device was substantially equivalent. |
| **Summary of Clinical Tests:** | Clinical Testing was not required for these products. |
| **Conclusion:** | The indications for use, technology and performance characteristics of the PlasmaBlade X 3.0S LIGHT devices are equivalent to the predicate devices. Therefore, the PlasmaBlade X 3.0S LIGHT is substantially equivalent to the predicates. |