October 21, 2024

Stryker Instruments
Miriam Giltinan
Senior Staff Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K242266
Trade/Device Name: PhotonBlade 3; PhotonBlade 3 Smoke Evacuation
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 1, 2024
Received: August 1, 2024

Dear Miriam Giltinan:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.10.21 12:58:00 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242266

Device Name

PhotonBlade 3;
PhotonBlade 3 Smoke Evacuation

Indications for Use *(Describe)*

The PhotonBlade 3 is a monopolar radiofrequency (RF) device coupled with illumination that 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, neurological, and breast procedures (including mastectomy and lumpectomy).

The PhotonBlade 3 Smoke Evacuation device is a monopolar RF device coupled with illumination that 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, neurological, and breast procedures (including mastectomy and lumpectomy), and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

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 Information

510(k) Owner/Submitter:	Stryker Instruments 1941 Stryker Way Portage, MI 49002 USA
Contact Person:	Miriam Giltinan Senior Staff RA Specialist Email: miriam.giltinan@stryker.com
Registration Number:	3015967359
Date Summary Prepared:	August 01, 2024

Device Name

Trade Name(s)/Model number(s):	PhotonBlade 3/0730-101-000 PhotonBlade 3 Smoke Evacuation/0730-102-000
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)
Classification Panel:	General & Plastic Surgery
Device Class:	Class 2
Product Code:	GEI

Predicate Device

Predicate: PlasmaBlade X3.0S Light (K193579)

Reference: PhotonBlade with Adaptive Smoke Evacuation (K191583)

Device Description

The PhotonBlade 3 (Model No: 0730-101-000) and PhotonBlade 3 Smoke Evacuation (Model No: 0730-102-000) devices are sterile, single use, electrosurgical devices. The devices have a monopolar electrode at the distal end, which delivers radiofrequency (RF) energy for cutting and coagulation of tissue. The electrode is located at the distal end of a rotatable and extendable shaft. The devices have integrated LED-based illumination. In addition, the PhotonBlade 3 Smoke Evacuation features integrated smoke evacuation tubing for removal of smoke generated by electrosurgery when connected to a smoke evacuation unit. A cable with a universal connector attaches the device to an IEC 60601 compliant electrosurgical generator.

Indications for Use

The PhotonBlade 3 is a monopolar radiofrequency (RF) device coupled with illumination that 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, neurological, and breast procedures (including mastectomy and lumpectomy).

The PhotonBlade 3 Smoke Evacuation device is a monopolar RF device coupled with illumination that 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, neurological, and breast procedures (including mastectomy and lumpectomy), and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

Substantial Equivalence Comparison

The predicate device has been identified as the PlasmaBlade X3.0S Light (K193579). Both subject and predicate devices share the same intended use, and similar indications for use and technological characteristics.

Intended Use Comparison

	PhotonBlade 3 **Subject Device**	**PhotonBlade 3 Smoke Evacuation** **Subject Device**	**PlasmaBlade X3.0S Light** **Predicate Device**
Classification	Class 2		Class 2
Product Code	GEI		GEI
Regulation	21 CFR 878.4400		21 CFR 878.4400
Regulation Name	Electrosurgical cutting and coagulation device and accessories		Electrosurgical cutting and coagulation device and accessories
Indications for Use	The PhotonBlade 3 is a monopolar radiofrequency (RF) device coupled with illumination that 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, neurological, and breast procedures	The PhotonBlade 3 Smoke Evacuation device is a monopolar RF device coupled with illumination that 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, neurological, and breast procedures	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.

	PhotonBlade 3 Subject Device	PhotonBlade 3 Smoke Evacuation Subject Device	PlasmaBlade X3.0S Light Predicate Device
	(including mastectomy and lumpectomy).	(including mastectomy and lumpectomy), and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.	
Type of Use	Rx only		Rx only
Conditions of Use	Single Use		Single Use

The subject and predicate devices share identical classification regulation and intended use. The subject devices add an indication for "breast procedures (including mastectomy and lumpectomy)" which falls within the intended use of the predicate device. The indication is supported by a systematic literature review.

The purpose of the systematic literature review was to demonstrate the safety and efficacy of monopolar RF devices for the indication "breast procedures (including mastectomy and lumpectomy)". A thorough review of the literature explored 1) the medical field and targeted treated populations applicable for the subject devices as well as those of the predicate and other relevant monopolar RF devices; 2) clinical data for predicate and other relevant monopolar RF devices; and 3) vigilance databases to assess safety. Performance was assessed using reported outcomes including drain output, flap perfusion, thermal tissue injury, length of hospital stay, and procedural success. Safety was assessed by reviewing adverse events/complications reported in both peer-reviewed publications and vigilance databases and sought to identify events that were specifically related to the device or procedure.

Stryker identified a total of 63 unique publications utilizing search criteria specific to predefined indications. These were screened for inclusion using predetermined criteria and a weighted appraisal scoring system. In addition to vigilance databases, a thorough full-text review of 10 manuscripts was performed providing supportive clinical efficacy and safety data that covered the stated indication. An additional 34 publications describing relevant safety information (not specific to the breast indication) were included for a comprehensive product safety assessment.

Results from the systematic literature review concluded that monopolar RF devices are safe and effective for use in the breast surgery indications. No new or unexpected risks were identified.

The data supports the assertion that the indication for "breast procedures (including mastectomy and lumpectomy)" falls within the intended use (cutting and coagulation of soft tissue) of the predicate and does not introduce new questions of safety and effectiveness.

Technological Characteristics Comparison

	PhotonBlade 3 **Subject Device**	**PhotonBlade 3 Smoke Evacuation** **Subject Device**	**PlasmaBlade X3.0S Light** **Predicate Device**
Mechanism of action/Principle of operation	RF Monopolar Energy		RF Monopolar Energy
Compatibility with Electrosurgical Unit (ESU)	Standard ESU complying to IEC 60601 standards		Dedicated ESU
Illumination Source	LED		LED
Illumination Location	Distal Shaft		Main handpiece body
Illumination Power Source	2x3V battery		USB plug straight to generator
Light Color	White		White
Smoke Evacuation Design	N/A	Integrated	Integrated
Smoke Evacuation Mode of Operation	N/A	Connect to commercially available smoke evacuation unit or suction/vacuum source	Connect to commercially available smoke evacuation unit or suction/vacuum source
Sterilization	Sterile, single use (EtO)		Sterile, single use (EtO)
Type of Patient Contact	External Communicating Device <24 hours, tested to ISO 10993-1 (Limited contact)		External Communicating Device <24 hours, tested to ISO 10993-1 (Limited contact)
Blade Material	Coated Stainless Steel		Coated Stainless Steel

The subject and predicate devices share the same or similar fundamental technological characteristics:

- Mechanism of action/principle of operation – RF Monopolar Energy
- Electrode – Coated Stainless Steel
- Patient Contact – Limited contact
- Illumination – LED
- Configuration – sterile (EO), single use
- Smoke Evacuation (applicable for PhotonBlade 3 Smoke Evacuation only) – Integrated smoke evacuation design.

Differences in technological characteristics between subject and predicate devices were noted for:

- Illumination location and power source – The location of illumination is at the distal shaft for the subject devices compared to the predicate device where it is located in the main handpiece body. The source of illumination for the subject devices is by 2 x 3V batteries compared to the predicate device which uses a USB plug to the generator.
  The reference device (PhotonBlade with Adaptive Smoke Evacuation, K191583) also contains illumination at the distal shaft which is powered by a 3V battery.

- Compatibility with ESU - The subject devices are to be connected with any IEC 60601 compliant ESU. The predicate device is designed to be used with its own dedicated ESU.

Results of verification and validation demonstrate that these differences do not introduce new questions of safety and effectiveness. The subject devices are at least as safe and effective as the predicate device.

Summary of Non-Clinical Testing

A suite of performance testing was conducted to demonstrate substantial equivalence with the predicate device. Testing requirements were determined by relevant standards and FDA Guidance *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery, issued March 9, 2020*.

Sterilization, Biocompatibility, Electrical Safety and EMC Testing were conducted to the following standards:

Standard	Title
ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
ISO 11737-1: 2018	Sterilization of health care products. Microbiological methods. Determination of a population of microorganisms on products
ISO 11737-2: 2019	Sterilization of medical devices. Microbiological methods. Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices Part 10: Tests for skin sensitization
ISO 10993-23:2021	Biological evaluation of medical devices Part 23: Tests for irritation
ISO 10993-11:2017	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]
ANSI AAMI IEC 60601-2-2: 2017	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
AIM Standard 7351731 Rev. 3.00 2021-06-04	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard

Performance Testing

A range of performance testing was conducted to confirm the subject devices perform as intended and are safe and effective for their intended use. The testing included:

- *Simulated Use Life Testing* to verify that the subject devices perform as intended during use.
- *Coag Verification Test* to verify that the subject devices are effective in spot coagulation.
- *Telescope Locking Force Test* to verify that the subject devices' telescoping mechanism locks and does not extend or collapse under reasonable force.
- *Telescope Bending Test* to verify that the telescope of the subject devices withstands reasonable bending forces.
- *Light (Lumen) Test* to verify that the subject devices provide adequate brightness of lighting.
- *Blade Bending Test* to verify that the subject devices meet the pre-defined electrode bending criteria.
- *Smoke Evacuation Test* (for PhotonBlade 3 Smoke Evacuation only) to verify that the device evacuates smoke.
- *Thermal Spread Testing* to evaluate the penetrating thermal damage of the subject devices. Thermal Spread testing (ex vivo) was completed across three porcine tissue types (muscle, skin and liver tissue) in accordance with FDA Guidance *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery,* issued March 9, 2020.

All pre-defined acceptance criteria for the above tests were met. Results from the testing confirm that the subject devices perform as intended and support a determination of substantial equivalence to the predicate.

Usability/Human Factors

The subject devices demonstrated safe and effective use for the intended users, intended use, and use environments in accordance with FDA Guidance "*Applying Human Factors and Usability Engineering to Medical Devices*", issued February 3, 2016.

Conclusion

The subject devices, in comparison with the legally marketed predicate, share the same intended use and operating principles. Performance testing demonstrate that the subject devices are at least as safe and effective as the predicate. Any differences between the subject and predicate devices do not raise any new or different types of questions of safety and effectiveness. A determination of substantial equivalence is supported.