September 9, 2025

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

Re: K250483
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, SFQ
Dated: February 19, 2025
Received: February 19, 2025

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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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)*

K250483

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, breast (including mastectomy and lumpectomy) and electrophysiology implant (for implantation, upgrade and revision of Cardiac Implantable Electronic Devices (CIED) and leads) 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, breast (including mastectomy and lumpectomy) and electrophysiology implant (for implantation, upgrade and revision of Cardiac Implantable Electronic Devices (CIED) and leads) procedures, 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.

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:	September 09, 2025

Device Name

Trade Name(s)/Model number(s):	PhotonBlade 3 PhotonBlade 3 Smoke Evacuation
Product Code:	GEI; SFQ
Classification Name:	Electrosurgical cutting and coagulation device and accessories; Electrosurgical, cutting & coagulation & accessories, for cardiac electrophysiology device implantation and revision
Regulation Number:	21 CFR 878.4400
Device Class:	Class 2

Predicate Device

Predicate: PhotonBlade 3; PhotonBlade 3 Smoke Evacuation (K242266)

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, breast (including mastectomy and lumpectomy) and electrophysiology implant (for implantation, upgrade and revision of Cardiac Implantable Electronic Devices (CIED) and leads) 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, breast (including mastectomy and lumpectomy), and electrophysiology implant (for implantation, upgrade and revision of Cardiac Implantable Electronic Devices (CIED) and leads) procedures, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

Substantial Equivalence Comparison

The modifications to the PhotonBlade 3 and PhotonBlade 3 Smoke Evacuation devices concern the indications for use and resulting labeling only. No modifications were required of the physical device. Therefore, mechanical and electrical design, materials, dimensions, sterilization, user profile and use environment are identical.

	PhotonBlade 3 PhotonBlade 3 Smoke Evacuation Subject Device	**PhotonBlade 3 PhotonBlade 3 Smoke Evacuation Predicate Device K242266**	**Comparison**
Intended use and Indications for Use Comparison			
Classification	Class 2	Class 2	Identical
Product Code	GEI; SFQ	GEI	Similar – new secondary product code added to reflect additional indication for electrophysiology procedures
Regulation	21 CFR 878.4400	21 CFR 878.4400	Identical
Regulation Name	Electrosurgical cutting and coagulation device and accessories: Electrosurgical, cutting & coagulation & accessories, for cardiac electrophysiology device implantation and revision	Electrosurgical cutting and coagulation device and accessories	Similar – new secondary product code added to reflect additional indication for electrophysiology procedures

	PhotonBlade 3 PhotonBlade 3 Smoke Evacuation Subject Device	PhotonBlade 3 PhotonBlade 3 Smoke Evacuation Predicate Device K242266	Comparison
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, breast (including mastectomy and lumpectomy) and electrophysiology implant (for implantation, upgrade and revision of Cardiac Implantable Electronic Devices (CIED) and leads) 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, breast (including mastectomy and lumpectomy), and	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 flap), ENT, gynecologic, orthopaedic, arthroscopic, spinal, neurological, and breast procedures (including mastectomy and lumpectomy), and for removing smoke	Different– Additional indication for electrophysiology procedures

	PhotonBlade 3 PhotonBlade 3 Smoke Evacuation Subject Device	PhotonBlade 3 PhotonBlade 3 Smoke Evacuation Predicate Device K242266	Comparison
	electrophysiology implant (for implantation, upgrade and revision of Cardiac Implantable Electronic Devices (CIED) and leads) procedures, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.	generated by electrosurgery when used in conjunction with an effective smoke evacuation system.	
Type of Use	Rx only	Rx only	Identical
Conditions of Use	Single Use	Single Use	Identical
Technological Comparison			
Mechanism of action/Principle of operation	RF Monopolar Energy	RF Monopolar Energy	Identical
Illumination Source	LED	LED	Identical
Smoke Evacuation Design (applicable for PhotonBlade 3 Smoke Evacuation product only)	Integrated	Integrated	Identical
Sterilization	Sterile, single use (EtO)	Sterile, single use (EtO)	Identical
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)	Identical
Blade Material	Coated Stainless Steel	Coated Stainless Steel	Identical

The subject and predicate devices share identical technological characteristics, classification regulation and intended use. The subject devices add an indication for "electrophysiology implant procedures (for implantation, upgrade and revision of Cardiac Implantable Electronic Devices (CIED) and leads)" which falls within the cleared intended use of the predicate device. The addition of this indication is supported by a systematic literature review and specific non-clinical bench testing.

Systematic Literature Review

The purpose of the systematic literature review was to demonstrate the safety and efficacy of monopolar RF devices for the indication "electrophysiology implant procedures (for implantation, upgrade and revision of Cardiac Implantable Electronic Devices (CIED) and leads)". 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 comparable RF devices;

2) clinical data for comparable monopolar RF devices; and 3) vigilance databases to assess safety. Performance was assessed using reported outcomes including lead damage, 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 64 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 7 manuscripts was performed providing supportive clinical efficacy and safety data that covered the stated indication. One additional publication describing relevant safety information (not specific to the electrophysiology 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 electrophysiology indications. No new or unexpected risks were identified.

The data supports the assertion that the indication for "electrophysiology implant (for implantation, upgrade and revision of Cardiac Implantable Electronic Devices (CIED) and leads) procedures" falls within the intended use (cutting and coagulation of soft tissue) of the predicate and does not introduce new questions of safety and effectiveness.

Summary of Non-Clinical Testing

No new biocompatibility, sterilization, or electrical/EMC testing was required to support the addition of the electrophysiology indication. Specific non-clinical bench testing was carried out to investigate the impact of the subject devices on CIED leads with test results confirming instructions within the labeling regarding safe use of the subject devices in the proposed electrophysiology indication. Testing was conducted ex vivo across a combination of power settings, modes, cut types and orientations. A polyurethane insulated lead model was selected as the worst-case lead type for testing. Lead damage was determined based on visual inspection and impedance measurement checks. The testing confirmed that in certain combinations of settings and orientations, the subject devices can be used in contact with CIED leads without causing an insulation breach.

Conclusion

The evidence provided within this submission demonstrates that the proposed indications are a subset of the intended use of the predicate (cutting and coagulation of soft tissue) and that the subject devices have the same intended use as the predicate.

The systematic clinical literature review conducted demonstrates that no new questions of safety or effectiveness are raised when PhotonBlade 3 devices are used in electrophysiology procedures. No different types of adverse events are seen in electrophysiology applications as compared to the currently cleared types of procedures.

The proposed devices are at least as safe and effective as the predicate devices when used for the proposed indications. There is no difference in technological characteristics between subject and predicate, as no physical design changes were required to allow the subject device for use in electrophysiology procedures. Therefore, a determination of substantial equivalence with the predicate device for the new indication is supported.