March 6, 2020

INVUITY, INC.
c/o Ms. Susanne Galin
Stryker Instruments
Principal Regulatory Affairs Specialist
444 De Haro Street
San Francisco, California 94107

Re: K191583
Trade/Device Name: PhotonBlade with Adaptive 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: February 5, 2020
Received: February 6, 2020

Dear Susanne Galin:

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 H. Chen
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)*

K191583

Device Name
PhotonBlade® with Adaptive Smoke Evacuation

Indications for Use *(Describe)*

The PhotonBlade® with Adaptive Smoke Evacuation is a monopolar RF device coupled with illumination that is indicated for cutting and coagulation of tissue during general surgical 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.

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5 510(k) Summary

Date Prepared: 05 March 2020

5.1 Regulatory authority

This 510(k) Summary is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990, 21 CFR 807.92

5.2 Company name:

INVUITY, INC.
444 De Haro Street
San Francisco, CA 94107

5.3 Contact person:

Susanne Galin, RAC
Principal Regulatory Affairs Specialist
Stryker Instruments, on behalf of:
Invuity, Inc.
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San Francisco, CA 94107
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5.4 Name of device

Trade Name:	PhotonBlade® with Adaptive Smoke Evacuation
Common Name:	Electrosurgical Cutting and Coagulation Device
Device Product Code:	GEI
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Device Panel:	General and Plastic Surgery
Device Classification:	Class II

5.5 Predicate device:

- PhotonBlade® (K162053)

Reference devices:

- Stryker® Neptune® E-SEP™ Smoke Evacuation Pencil (K160693)
- Medtronic PEAK PlasmaBlade 3.0S (K093695)

5.6 Device modifications:

Subject device modifications without change to fundamental scientific technology and intended use;

- Changes to the internal components and external components of the telescoping shaft and electrode to improve the electrical insulation
- Update to PCBA LED driver circuit component to reduce susceptibility to RF interference, resulting in a more consistent illumination function

Device modification with change to fundamental scientific technology and intended use;

- The proposed device incorporates an Adaptive Smoke Evacuation component

5.7 Device description

The PhotonBlade® with Adaptive Smoke Evacuation (PB2SE) is a single use, sterile, electrosurgical device with a light and adaptive smoke evacuation attachment.

The device has a monopolar electrode at the distal tip, which delivers Radiofrequency (RF) energy for cutting and coagulation of tissue. The electrode tip is located at the distal end of a rotatable and extendable shaft. The adaptive smoke evacuation attachment connects to the telescoping shaft and the cable of the PhotonBlade. It incorporates a barb connector at the end of the tubing to allow connection to a secondary suction hose connected to a smoke evacuation system. The device handle is integrated with controls for cut, coagulation, and illumination (light). A universal cable attaches the device to a 510(k) cleared electrosurgical unit.

5.8 Indications for Use Statement

The PhotonBlade® with Adaptive Smoke Evacuation is a monopolar RF device coupled with illumination that is indicated for cutting and coagulation of tissue during general surgical procedures and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

5.9 Comparison of Technological Characteristics

The predicate for the PB2SE electrosurgical pencil portion of the device has been identified as the previously cleared PhotonBlade® (K162053). The pencils utilize monopolar RF energy for cutting and coagulation via an insulated metal electrode. Both pencils share the same technological characteristics, operating principles and performance characteristics.

The Stryker® Neptune® E-SEP™ Smoke Evacuation Pencil (K160693) has been identified as a reference device for the smoke evacuation portion of the PB2SE. The reference ESEP pencil is used to demonstrate that the addition of a smoke evacuation function to the PB2SE electrosurgical pencil is established in a similar manner. Both electrosurgical pencils incorporate a smoke channel to remove the smoke produced from general surgical procedures utilizing electrosurgical cutting and coagulation. Both require suction from an independent smoke evacuation system to remove smoke. The devices have the same

intended use and similar technological characteristics. Additionally, the Medtronic PEAK PlasmaBlade 3.0S (another RF monopolar electrosurgical pencil with integrated smoke evacuation tubing) is referenced as it has similar dimensions of smoke evacuation tubing.

Table 5.9-1 Comparison to Predicate and Reference Devices

Attribute	**Invuity PhotonBlade® with Adaptive Smoke Evacuation (PB2SE)** **Subject Device**	**Invuity PhotonBlade (PB1) (K162053)** **Predicate**	**Stryker® Neptune® E-SEP Smoke Evacuation Pencil (E-SEP) (K160693)** **Reference**	**Medtronic PEAK PlasmaBlade 3.0S (K093695)** **Reference**
General Characteristics				
Indications for Use	The PhotonBlade® with Adaptive Smoke Evacuation is a monopolar RF device coupled with illumination that is indicated for cutting and coagulation of tissue during general surgical procedures and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.	The Photonblade is a monopolar RF device coupled with illumination that is indicated for cutting and coagulation of tissue during general surgical procedures.	The Neptune E-SEP is an Integrated Smoke Evacuation Pencil (pencil) designed for general electrosurgical applications including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit (generator) to the operative site for the desired surgical effect.	The PEAK PlasmaBlade 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.
Principal of Operation	RF Monopolar electrosurgical cutting and coagulation	RF Monopolar electrosurgical cutting and coagulation	N/A – comparing to PB1 predicate	N/A – comparing to PB1 predicate
Method of Operation	Push-Button activation of electrosurgical energy.	Push-Button activation of electrosurgical energy, smoke evacuation controlled by a smoke evacuation unit.		
Rated Voltage	3000 V	3000 V		

Electrode	Stainless steel with insulating enamel	Stainless steel with insulating enamel		
Illumination Function				
Illumination Source	LED	LED	N/A – comparing to PB1 predicate	N/A – comparing to PB1 predicate
Nominal Light Output	29 Lumens	28 Lumens		
Light Color	White	White		
Smoke Evacuation Function				
Mode of Operation	Commercially available smoke evacuation unit or suction/vacuum source	N/A – comparing to E-SEP reference	Commercially available smoke evacuation unit or suction/vacuum source	Commercially available smoke evacuation unit or suction/vacuum source
Smoke Evacuation Design	Adaptive - tubing can be adjusted proximally or distally and is attached alongside the telescoping shaft, handpiece, and cord. Barb connector at the proximal end of the adaptive smoke tubing mates to a tube or hose connected to a suction source		Integrated – smoke evacuation channel integrated into the shaft of the pencil, extending off proximal end of pencil and to the suction source	Integrated – smoke evacuation channel integrated into the shaft of the pencil. Barb connector at the proximal end of the adaptive smoke tubing mates to a tube or hose connected to a suction source
Tube Dimensions	Inner Diameter – 3 mm Length – 0.762 m		Inner Diameter – 10 mm Length – 3 m	Inner Diameter – 2.54 mm Length – approximately 0.76 m
Method for occlusion	Mechanical occlusion with a pinch clamp		No method for occlusion	Mechanical occlusion with a pinch clamp
Biological Characteristics				
Electrode Material	400-series stainless steel with enamel (porcelain) insulation and outer fluorinated ethylene propylene (FEP) insulation	400-series stainless steel with enamel (porcelain) insulation and outer fluorinated ethylene propylene (FEP) insulation	N/A – comparing to PB1 predicate	N/A – comparing to PB1 predicate
Smoke Tubing Material	Polyvinyl chloride (DEHP-free)	N/A – comparing to E-SEP reference	Ethylene vinyl acetate	N/A – comparing to E-SEP reference
Housing Material including	Makrolon 2458 Polycarbonate	Makrolon 2458 Polycarbonate	N/A – comparing to PB1 predicate	N/A – comparing to PB1 predicate

buttons, Smoke Tubing Clip Material		(does not have clips)		
Telescoping Shaft Material	Polyethylene Terephthalate (PET)	Polyethylene Terephthalate (PET)	N/A – comparing to PB1 predicate	N/A – comparing to PB1 predicate
Waveguide	Zeon Zeonex 690R COP	Zeon Zeonex 690R COP	N/A – comparing to PB1 predicate	N/A – comparing to PB1 predicate
Sterilization Method	EtO	EtO	EtO	EtO
Sterility Assurance Level	1×10^{-6}	1×10^{-6}	1×10^{-6}	1×10^{-6}
Duration and type of patient contact	Limited contact with tissue	Limited contact with tissue	Limited contact with tissue	Limited contact with tissue

Technological Similarities

PhotonBlade® vs. PhotonBlade® with Adaptive Smoke Evacuation

Fundamentally, the PB1 and PB2SE surgical pencils are based on the same intended use and technological elements.

- Energy – Monopolar, Radiofrequency energy
- Electrode – Insulated metal electrode
- Principle of Operation – Electrosurgical cutting and coagulation of tissue
- Illumination
- Configuration (sterile, single-use)

Stryker® Neptune® E-SEP™ Smoke Evacuation Pencil vs. PhotonBlade® with Adaptive Smoke Evacuation

The PB2SE and E-SEP have the same principle of operation as it relates to smoke evacuation. Both devices are designed to incorporate a smoke channel. Both devices require vacuum or suction from an independent source for smoke removal capability.

Medtronic PEAK PlasmaBlade 3.0S vs. PhotonBlade® with Adaptive Smoke Evacuation

The PEAK PlasmaBlade 3.0S and the PB2SE also have the same principle of operation as it relates to smoke evacuation. Both devices are designed to incorporate a smoke evacuation channel, and both devices require vacuum or suction from an independent source for smoke removal capability. Comparatively, the size of the smoke evacuation tubing is very similar in both length and inner diameter. Additionally, the PEAK PlasmaBlade 3.0S is also aligned to the PB2SE in that it also requires an intermediate suction tube to connect to a vacuum source, and features a pinch clamp to occlude the smoke evacuation tubing should it be required.

Technological Differences

PhotonBlade® vs. PhotonBlade® with Adaptive Smoke Evacuation

Two changes made to the predicate PB1 are subjects of this submission. One change (difference) involved improvements to electrical insulation components in the electrode and telescoping shaft (internal and external components). A second change (difference) involved an update to the PCBA LED driver circuit component.

Stryker® Neptune® E-SEP™ Smoke Evacuation Pencil vs. PhotonBlade® with Adaptive Smoke Evacuation

The following technological differences exist between the subject and reference device:

- The smoke evacuation tubing material – The E-SEP uses Ethylene Vinyl Acetate (EVA) and the PB2SE uses DEHP-free polyvinyl chloride.
- The smoke tube dimension – The E-SEP uses a longer tube with a larger lumen diameter than the PB2SE (Medtronic PEAK PlasmaBlade reference device is similar in smoke evacuation tube dimensions).
- The subject device requires an intermediate suction hose while the reference connects directly to the smoke evacuation system (Medtronic PEAK PlasmaBlade reference device is the same in that it requires an intermediate suction hose).
- The subject device has an occlusion feature to shut off the suction in case the tube becomes blocked and the reference does not (Medtronic PEAK PlasmaBlade reference device is the same in that it has an occlusion feature in the form of a pinch clamp).

5.10 Performance Data

The PB2SE features the same operating principle and manufacturing processes, and similar technology as compared to the PB1. Testing has been performed on the device materials, components, sub-assemblies, and final assemblies to confirm the safety and effectiveness of the device.

Performance testing was conducted on the PB2SE to demonstrate compliance with the product requirements, safety and effectiveness, and substantial equivalence to the predicate.

The following product performance tests were completed; biocompatibility, performance testing, and electrical safety/electromagnetic compatibility.

Biocompatibility

Per the “Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,” (FDA guidance, June 2016) and ISO 10993-1:2009/(R)2013, the device falls into the category external communicating device, tissue contact, less than 24- hour duration.

The only new contacting material introduced with the subject device is the smoke evacuation tubing. Biocompatibility testing was performed on the material and confirmed to be biocompatible for its intended use.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety testing and EMC testing were conducted per IEC 60601-1:2005 + A1:2012 with US deviation, IEC 60601-2-2:2017 (6th Edition) and IEC 60601-1-2:2014 (4thEdition), and AIM 7351731 Rev 2.00 standards. The device complies with the relevant sections of the standards.

Mechanical and Functional Testing

Mechanical and functional testing were performed on conditioned samples (EtO sterilization, distribution simulation, and 24 months accelerated aging) to confirm design inputs. The results confirm the product meets the specifications and acceptance criteria.

Smoke Evacuation

No standard requirements specific to the smoke performance exist, however, tests were conducted with the device to verify the device meets the design requirements, performance specifications, and intended use. The design of the smoke evacuation attachment does not affect or change the function of the electrosurgical device. The smoke evacuation flow rate was evaluated and compared between the PB2SE and the reference device PEAK PlasmaBlade 3.0S, demonstrating equivalent or better flow rate. The intake portion of the device did not obstruct the electrosurgical function of the pencil, while removing smoke. The results demonstrate the product is safe, effective, and meets the requirements for technology, performance and intended use.

5.11 Conclusion

The data presented for the PhotonBlade® with Adaptive Smoke Evacuation with respect to the device function, intended use, technological, and biological characteristics demonstrate that it is as least as safe and effective as the predicates. Any differences between the subject device and the predicate/reference devices do not raise any different issues of safety and effectiveness. A determination of substantial equivalence is supported.