DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 15, 2016

Invuity, Inc.
Mr. John Kang
Senior Director, Quality Assurance and Regulatory Affairs
444 De Haro Street
San Francisco, California 94107

Re: K162053
Trade/Device Name: PhotonBlade
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 20, 2016
Received: July 25, 2016

Dear Mr. Kang:

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. 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 Part 803); good manufacturing practice requirements as set forth

in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162053

Device Name
PhotonBlade™

Indications for Use *(Describe)*
The PhotonBlade is a monopolar RF device coupled with illumination that is indicated for cutting and coagulation of tissue during general surgical 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.

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5 510(K) SUMMARY

Date Summary Prepared July 20, 2016.

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:

John Kang
Senior Director RA/QA
INVUITY, INC.
444 De Haro Street
San Francisco, CA 94107

5.4 Name of device

Trade Name:	PhotonBlade™
Common Name:	Electrosurgical Accessory
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(s):

- PEAK Surgical PlasmaBlade 3.0S (K093695)
- PARE NOVA ES Pencil with Surgical Light Source (K944363)

5.6 Device description

The PhotonBlade is a single use, sterile, electrosurgical device with a light. The PhotonBlade has an electrode at the distal tip, which delivers RF energy for cutting and coagulation of soft tissue. The electrode tip is located at the distal end of a rotatable and extendable shaft. 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.

5.7 Indications for Use statement

The PhotonBlade™ is a monopolar RF device coupled with illumination that is indicated for cutting and coagulation of soft tissue during general surgical procedures.

5.8 Substantial equivalence comparison

Two predicates have been identified for the PhotonBlade, PlasmaBlade 3.0S and NOVA ES Pencil. In terms of the indications for use, the PlasmaBlade 3.0S and the NOVA ES Pencil are predicates for soft tissue cutting and coagulation and the NOVA ES Pencil is a predicate for surgical light (illumination).

Comparison to Predicate Device(s)

Attribute	Invuity PhotonBlade Subject Device	PEAK Surgical PlasmaBlade (Medtronic) K093695
Intended Use	The PhotonBlade is intended for soft tissue dissection and coagulation coupled with illumination for use in General Surgical procedures.	The Peak PlasmaBlade is intended for soft tissue dissection and coagulation for use in General, Plastic, and Orthopedic surgical procedures.
Principle of Operation	Electrosurgical cutting and coagulation	Electrosurgical cutting and coagulation
Anatomical Site(s)	Soft Tissue	Soft Tissue
Use	Single Use	Single Use
Materials	Metal electrode/enamel insulator	Metal electrode/enamel insulator
Specification		
Energy Type	Radiofrequency (RF)	Radiofrequency (RF)
Power Modes	Monopolar	Monopolar
Electrode	Stainless steel blade insulated with enamel	Stainless steel blade insulated with enamel
Compliance		
Sterilization	Sterile-Ethylene Oxide	Sterile-Ethylene Oxide
EMC & Electrical Safety Testing	IEC 60601-1 3rd Edition IEC 60601-2-2	IEC 60601-1 2nd Edition
Biocompatibility	ISO 10993-1	ISO 10993-1

Comparison to Predicate Device(s)-Illumination (Lighted ES Pencil)

Attribute	Invuity PhotonBlade Subject Device	PARE Surgical NOVA ES (Electrosurgical) Pencil with Light K944363
Illuminate Surgical Field	Yes	Yes
Illumination source	LED	LED
Illumination location	Shaft	Handle
Nominal Light Output	28 lumens (n=29)	30 lumens (n=1)
Illumination power source	3V Battery	3V Battery
Battery characteristic	Replaceable	Non-replaceable
Light Color	White	White

5.9 Technological Characteristics

The PhotonBlade device is similar to both predicate devices in that they are electrosurgical instruments used to cut and coagulate soft tissue utilizing RF energy.

PhotonBlade and PlasmaBlade both have insulated electrodes that extend and rotate. Both devices utilize blade electrodes where only the edge of the blade is exposed or active. As such, the principles of operation involved in cutting and coagulation of tissue are the same on either device. The differences between the PhotonBlade and PlasmaBlade are:

- The PlasmaBlade device has aspiration and the PhotonBlade does not.
- The PlasmaBlade is compatible with a dedicated electrosurgical unit (ESU) or generator and the PhotonBlade is intended for use with general purpose FDA-cleared RF generators with the standard or traditional (Bovie) three plug receptacle, such as the Valleylab (Medtronic) Force FX c and Conmed S5000 for example.
- The PhotonBlade has a light and the PlasmaBlade does not.

The PhotonBlade and NOVA ES Pencil lights both provide illumination using LED technology. In both devices, the illumination is powered by a battery; however, the PhotonBlade battery is replaceable, while the NOVA ES Pencil battery is not. The NOVA ES Pencil electrode tip is not insulated, and the device is provided with two tip configurations (one long and one short). The

PhotonBlade has an insulated tip with only one configuration that can be adjusted via an extendable shaft. The NOVA ES Pencil has three LEDs that are located in the handle of the device; the distance from the electrode tip to the LEDs varies depending on the tip configuration. The PhotonBlade has one LED that is located in the shaft of the device; the distance from the electrode tip to the LED is constant (approx. 2cm).

The differences identified between the PhotonBlade and its two predicates (PlasmaBlade and NOVA ES Pencil Surgical Light Source) do not present any new concerns of safety and effectiveness.

5.10 Summary of Performance Data

Performance testing was conducted on PhotonBlade devices that were exposed to EO sterilization and simulated transportation to demonstrate compliance with the product requirements and to demonstrate safety, efficacy, and substantial equivalence to the predicate. The following product performance tests are included: mechanical, electrical safety/electromagnetic compatibility, operational, *ex-vivo* thermal effects on tissue comparisons, biocompatibility, and packaging evaluation. Product Shelf Life studies for 7 months and 37 months will be conducted.

Like the predicate device(s), no clinical testing was necessary to support substantial equivalence. The data submitted support the substantial equivalence claim for the proposed indications for use; the PhotonBlade is as safe and effective as the predicate device(s).

5.11 Conclusion

Invuity Inc. considers the PhotonBlade device to be substantially equivalent to the legally marketed predicate device(s) with respect to the device function, intended use, and patient population. Any differences in technological characteristics between the PhotonBlade device and the predicate device(s) do not raise any new issues of safety and effectiveness. The Invuity PhotonBlade is substantially equivalent to the proposed predicate devices.