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

June 23, 2016

JustRight Surgical LLC
Ms. Jenifer Kennedy
Director of Research
357 S. McCaslin Boulevard, Suite 120
Louisville, Colorado 80027

Re: K160602
Trade/Device Name: JustRight Surgical Vessel Sealing System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 24, 2016
Received: May 26, 2016

Dear Ms. Kennedy:

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 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 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 yours,

David Krause -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)*

K160602

Device Name
JustRight Surgical® Vessel Sealing System

Indications for Use *(Describe)*

The JustRight Surgical® Vessel Sealing System is indicated for use in open and laparoscopic general surgical procedures to seal blood vessels and vascular bundles up to and including 5 mm in diameter for use in adult and pediatric populations, wherever vessel ligation is required.
The device is contraindicated for use in ENT 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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K160602
510(K) SUMMARY
Prepared In accordance with 21 CFR Part 807.92

Submitter Information

Submitter's Name:	JustRight Surgical LLC
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Contact Person:	Jenifer Kennedy
Telephone:	720-287-7143 720-287-7135 (fax)

Date Prepared:	June 21, 2016
Device Trade Name:	JustRight Surgical® Vessel Sealing System
Classification:	Class II
Product Code(s):	GEI
Common Name:	Electrosurgical, Cutting & Coagulation and Accessories
Regulation Number(s):	878.4400
Predicate Devices:	JustRight Surgical® Vessel Sealing System K123662 LigaSure™ Vessel Sealing System K981916 Force Triad™ Electrosurgical Generator K070162

Intended Use:
The JustRight Surgical® Vessel Sealing System is indicated for use in open and laparoscopic general surgical procedures to seal blood vessels and vascular bundles up to and including 5 mm in diameter for use in adult and pediatric populations, wherever vessel ligation is required.

The device is contraindicated for use in ENT procedures.

Device Description/Technological Characteristics:
The JustRight Surgical® Vessel Sealing System consists of the JustRight™ Generator and a JustRight™ Sealer. The JustRight™ Generator is designed to provide low power bipolar RF energy for vessel-sealing applications. The JustRight™ Generator is for use only with JustRight™ Sealer instruments. The JustRight™ Sealer is a hand held ring handle design with either a 10 cm or a 20 cm shaft length that is compatible with a 3mm (ID) cannula. The JustRight™ Sealer attaches to the generator via a 10' cord.

Performance Data:
Bench testing of the JustRight Surgical® Vessel Sealing System was performed to evaluate device function and durability. Electrical safety and Electromagnetic Compatibility testing was conducted in accordance with IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-2-2.

Biocompatibility testing was conducted in accordance with ISO 10993.

Animal testing of the JustRight Surgical® Vessel Sealing System conducted, confirmed device performance to be equivalent to the predicate device.

Conclusions Drawn From Non-clinical Performance Testing
The results of bench testing performed confirmed that the device performance and characteristics performed as well as the currently marketed device and are consistent with safety and performance requirements for this device type and intended use.

Safety and Efficacy Considerations
A literature review, including meta-analytics, was conducted to evaluate complication rates noted for vessel sealers in pediatric populations compared to adult populations. In addition, post-market feedback data was collected on the JustRight Surgical® Vessel Sealing System. This information supports the expansion of the device indication for use in the pediatric population.

Substantial Equivalence:
The current JustRight Surgical® Vessel Sealing System is very similar to the cleared JustRight Surgical® Vessel Sealing System. The indication for use statement has been modified to include an indication for pediatric use in general and laparoscopic surgical procedures. The literature review and postmarket feedback evaluations provide supporting safety and efficacy information for the pediatric indication There is no change to the tissue types or types of procedures where the JustRight Surgical® Vessel Sealing System is indicated. The technical specifications of the current device are the same as the JustRight predicate device.

In consideration of the evidence provided to support the pediatric indication, and the comparison of both technical and use features of the JustRight Surgical® Vessel Sealing System, the subject device is substantially equivalent to the JustRight Surgical® Vessel Sealing System (K123662) and Covidien LigaSure™ Vessel Sealing System (K981916, K070162).