DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2015

EndoPrime Incorporated
Mr. Rich Grant
Chief Executive Officer
4480 Lake Forest Drive, Suite 414
Cincinnati, Ohio 45242

Re: K150271
Trade/Device Name: Prime™ Adaptive Ultrasonic Scalpel System
Regulatory Class: Unclassified
Product Code: LFL
Dated: May 18, 2015
Received: May 20, 2015

Dear Mr. Grant:

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" (21CFR 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,

Jennifer R. Stevenson -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)*
Pending K150271

Device Name
Prime™ Adaptive Ultrasonic Scalpel System

Indications for Use *(Describe)*
The Prime™ Adaptive Ultrasonic Scalpel System is a cutting and coagulation system indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection, otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provided with each instrument). The system can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

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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510(k) Summary

Date Prepared: **May 29, 2015** (REVISED)
Submitter Contact: Rich Grant, CEO
EndoPrime, Inc.
4480 Lake Forest Drive, Suite 414
Cincinnati, OH 45242
513-769-1916

Regulatory Contact: Rich Grant
EndoPrime, Inc.
4480 Lake Forest Drive, Suite 414
Cincinnati, OH 45242
513-769-1916

Trade Name: The Prime™ Adaptive Ultrasonic Scalpel System
Common or Usual Name: Ultrasonic Surgical Instruments
Product Class: Class II
Classification: Instrument, Ultrasonic Surgical
Product Codes: LFL
Panel Code: General & Plastic Surgery
Regulation Standard: Unclassified

Reason for this Submission: This Traditional 510(k) involves one medical device system compiled of three individual medical device components.

No Prior Submissions: There were no prior submissions for the subject device by EndoPrime Inc.

Indications for Use:

The **Prime™ Adaptive Ultrasonic Scalpel System** is a cutting and coagulation system indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection, otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provided with each instrument). The system can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

Device Descriptions:

The **Prime™ Adaptive Ultrasonic Scalpel System** has three major components: Generator (with footswitch), Transducer Handpiece and instruments (or blades). The **Prime™ 6000 Generator** provides input/output control and operation interface to automatically adapt the

ultrasonic power output for the tissue load encountered. The device system is compliant with the following consensus standards:

Performance Standards:	
IEC 60601-1 2005 + CORR. 1 (2006) + CORR. (2007)	International Standard-Medical Electrical Equipment-General Requirements for Basic Safety and Essential Performance.
CAN/CSA-C22.2 No. 60601-1:08	Medical Electrical Equipment-Part 1-6: General Requirements for Safety-Collateral Standard; General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.
EN 60601-1-2:2007 CISPR 11:2009+A1	Medical Electrical Equipment-Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.
IEC 60601-1-2-18:2009 (Third Edition)	Medical electrical equipment-Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.
IEC 61000-4-8:2010	Medical Electrical Equipment: Part 1-4: General Requirements for Collateral Standard: Programmable Electrical Medical Systems.
IEC 61000-3-2:2006 +A1 +A2	Electromagnetic compatibility (EMC)-Part 3-2: Limits for harmonic current emissions (equipment input current ≤ 16 A per phase).
IEC 61000-3-3:2008	Electromagnetic compatibility (EMC)-Part 3-3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection.
IEC 61000-4-3:2006 + A1:2007 + A2:2010	Electromagnetic compatibility (EMC)-Part 4-3: Limits-Limitation of emission of harmonic currents in low-voltage power supply systems for equipment with rated current greater than 16 A.
IEC 61000-4-4:2004+A1:2010	Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test.
IEC 61000-4-5:2005	Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test.
IEC 61000-4-6:2003	Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields.
IEC 61000-4-11:2004	Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests.
ISO 10993-1:2009/AC2010	Biocompatibility Evaluation of medical Device Table A.1
ISO 10993-5:2009	Biological evaluation of medical devices--Part 5: Tests for

	vitro cytotoxicity.
ISO 10993-10:2009	Biological evaluation of medical devices--Part 10: Test for irritation and skin sensitivity.
ISO 10993-11:2009	Biological evaluation of medical devices--Part 11: Tests for systemic toxicity.
ISO 10993-4:2009	Biological evaluation of medical devices—Part 4: Test for Hemocompatibility.
AAMI TIR30:2011	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD249).
EN/ISO 14971:2012	Risk Management for Medical Device
EN/IEC 62304:2006	Medical device software—Software life cycle processes.

Prime™ Adaptive Ultrasonic Scalpel System and Blades family of products consist of:

Prime™ G6000 Generator provides operation interface display, device condition monitoring and Input/Output control. The generator provides electrical energy output to the transducer, which is controlled by activating the footswitch. The **Prime™ G6000 Generator** is also validated to operate with hand switched devices and hand switched enabled transducer hand pieces. A built-in, automatic pre-check function verifies proper connection and operation of the system during startup and continuously monitors the system and instruments. Variable and Maximum (or Full) power levels (1 through 5) are displayed on the front panel and can be selected by pressing the VAR or FULL footswitch pedal (or if available the hand switch). The Variable Power setting can be selected throughout the procedure to provide corresponding energy outputs with the interacting instrument. Audible and visual alarms assist with identifying anomalies, error, and failures including generator, instrument or transducer that are at the end of their useful life. A Standby button is available to pause the system to avoid accidental activation when not in use, or conduct manual system checks and diagnostics.

Prime™ Ultrasonic Scalpel Reusable Blades vibrate ultrasonically, which enables its cutting ability. The same vibration seals small vessels (≤ 2mm) with coagulated blood and tissue proteins by producing local heating of tissue. Homeostasis occurs when tissue couples with the blade. The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed for use with a transducer and a generator system as part of the **Prime™ Adaptive Ultrasonic Scalpel System** and family of products; these products are compatible with a limited number of other manufacturer's systems. The system instruments can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels with the advantages of limited heat/smoke generation and the lack of current flow through the patient. The blade instruments are provided with a reusable Torque Wrench to assure proper tightness when attaching the blade to the transducer. The generator will automatically check the tightness to assure proper function.

The **Prime™ Reusable Transducer Handpiece** cooperates with the **Prime™ Adaptive Ultrasonic Scalpel Blades** as a cutting and coagulation instrument. The **Prime™ Reusable Transducer Handpiece** is designed to convert electrical energy from the generator to mechanical motion of the instrument blades. When the transducer is used in conjunction with the **Prime™ Adaptive Ultrasonic Scalpel System**, the transducer provides ultrasonic vibration, which enables the blade's cutting ability. **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products is compatible with a limited number of other manufacturer's systems.

Prime™ Adaptive Ultrasonic Scalpel System products are compatible with a limited number of other predicate systems.

Predicate Device(s):

K002981-Ultracision® Harmonic Scalpel®, Ethicon Endo-Surgery, Inc.
K990430-Ultracision® HARMONIC Scalpel® Hand Piece, Ethicon Endo-Surgery
K010898-Ultracision Harmonic Scalpel Blade, Ethicon Endo-Surgery
K053056-Harmonic Scalpel Blades and Shears, Ethicon Endo-Surgery, Inc.

Prime™ Adaptive Ultrasonic Scalpel System blade tips are finished identical to other ultrasonic devices:

Reference Device:

K010309-Sonopet® Surgical Aspirator, Mutoh America CO., LTD. (now Stryker) refinanced for its blue anodized blade tip surface only.

Technological Characteristics:

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** technological characteristics are substantially equivalent to the predicated devices including automatically adapting the ultrasonic power output for the tissue load encountered to provide consistent vibration in differing loads and tissue thickness. The predicate device scalpel blades were predicated on reusable scalpel blades and the **Prime™ Ultrasonic Scalpel Reusable Blades** are designed to function similar to the predicate devices but are provided non-sterile and validated for disassembly, cleaning and sterilization. Another feature of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** is the ability to disconnect the cable at the transducer handpiece. This feature allows the surgical scrub technician to quickly replace the transducer handpiece and/or ultrasonic blades without contact with the non-sterile surface of the generator or assistance from others. The cable disconnect was designed as a convenience feature similar to the ability to disconnect at the generator. The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed similar to the predicate blades but have slightly different end effector designs. The **Prime™ Ultrasonic Curved Blades** have a compact design to improve access in narrow, delicate anatomy. The **Omni™ Ultrasonic Hook Blades** are curved for better visibility with a duel hook design to permit easier change of direction without full rotation. These technological improvements will not affect the overall device intended use, performance characteristics, substantial equivalence to the predicate, or raise any new issues regarding safety or efficacy.

Conclusion:

EndoPrime, Inc. concludes that the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products, is substantially equivalent to the predicate devices, and raises no new questions of safety or effectiveness.