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

Oreon Technologies Inc.
% Mr. Howard Fidel
President
520 White Plains Road
TARRYTOWN NY 10591

May 5, 2016

Re: K153620
Trade/Device Name: Enovare Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, IYN, IYX
Dated: December 18, 2015
Received: February 22, 2016

Dear Mr. Fidel:

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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K153620

Device Name
Enovare Ultrasound System

Indications for Use *(Describe)*
The Enovare system's ultrasound scanner connected with a probe enables real time diagnostic ultrasound imaging for B-mode, Tissue and Contrast Harmonic Imaging, PWD, Power Doppler, Color Doppler and combined mode imaging. Signal Analysis and display. Guidance of biopsy and therapy needles, geometrical measurements and calculation of parameters. The system offers optional probes each type optimized to image structure and orientation of tissues during specific clinical applications. These include general Abdominal, Intraoperative, Cardiac, Neurosurgery, Transrectal, Small organs, Urological, Transvaginal, Musculoskeletal.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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System: _Enovare_____ _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Modes of Operation

Track 3	*B*	*PWD*	*Color Doppler + B*	*Color + PWD+B*	*Harmonic*
Abdominal	*p*	*n*	*n*	*n*	*n*
Intra-operative (abdominal)	*n*	*n*	*n*	*n*	*n*
Laparoscopic	*n*	*n*	*n*	*n*	*n*
Trans-rectal	*p*	*n*	*n*	*n*	*n*
Trans-vaginal (not fetal)	*p*	*n*	*n*	*n*	*n*
Small Parts	*p*	*n*	*n*	*n*	*n*

n= new indication, p = previously cleared by FDA

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Concurrence of CDRH

System: _Enovare_____ Transducer: Intraoperative 2001114 _____
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Modes of Operation

Track 3	***B***	***PWD***	***Color Doppler + B***	***Color + PWD+B***	***Harmonic***
Abdominal					
Intra-operative (abdominal)	***n***	***n***	***n***	***n***	***n***
Laparoscopic	***n***	***n***	***n***	***n***	***n***
Trans-rectal					
Trans-vaginal (not fetal)					
Small Parts					

n= new indication, p = previously cleared by FDA

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Concurrence of CDRH

System: _Enovare_____ Transducer: Intersect™ 2001017 _____
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Modes of Operation

Track 3	*B*	*PWD*	*Color Doppler + B*	*Color + PWD+B*	*Harmonic*
Abdominal					
Intra-operative (abdominal)					
Laparoscopic					
Trans-rectal	*p*	*n*	*n*	*n*	*n*
Trans-vaginal (not fetal)	*p*	*n*	*n*	*n*	*n*
Small Parts					

n= new indication, p = previously cleared by FDA

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Concurrence of CDRH

System: _Enovare_____ Transducer: Linear 2001021 _____
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Modes of Operation

Track 3	***B***	***PWD***	***Color Doppler + B***	***Color + PWD+B***	***Harmonic***
Abdominal	***p***	***n***	***n***	***n***	***n***
Intra-operative (abdominal)					
Laparoscopic					
Trans-rectal					
Trans-vaginal (not fetal)					
Small Parts	***p***	***n***	***n***	***n***	***n***

n= new indication, p = previously cleared by FDA

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Concurrence of CDRH

510(k) Summary

I. SUBMITTER

Oreon Technologies Inc.
Suite 500
520 White Plains Road
Tarrytown, NY 10591

Phone: 914 413 0087
Email: howard@oreonetch.com

Contact Person: Howard Fidel
Date Prepared: October 25, 2015

II. DEVICE

Name of Device: Enovare
Common or Usual Name: Diagnostic Ultrasound System
Classification Names:
Ultrasonic Pulsed Echo Imaging System (90 IYO CFR 892.1560)
Ultrasonic Pulsed Doppler Imaging System (90 IYN, CFR 892.1560)
Diagnostic Ultrasound Transducer (90 ITX, CFR 892.1570)
Regulatory Class: II

III. PREDICATE DEVICES

B & K Medical Flex Focus 1202, K123254

3G Ultrasound Sonalis K043189

IV. DEVICE DESCRIPTION

The Enovare supports the following scanning modes and combinations thereof:
B-mode (incl. Tissue Harmonic Imaging), PWD mode, CFM mode, Amplitude (Power) Doppler mode.
The system consists of:

- system cart
- keyboard
- ultrasound probe(s)
- LCD monitor

The system can perform simple geometric measurements and perform calculations in the vascular and urology areas.

V. INDICATIONS FOR USE

The Enovare system's ultrasound scanner connected with a probe enables real time diagnostic ultrasound imaging for B-mode, Tissue and Contrast Harmonic Imaging, PWD, Power Doppler, Color Doppler and combined mode imaging. Signal Analysis and display. Guidance of biopsy and therapy needles, geometrical measurements and calculation of parameters. An optional 3-D unit can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.

The system offers optional probes each type optimized to image structure and orientation of tissues during specific clinical applications. These include general Abdominal, Intraoperative, Cardiac, Neurosurgery, Transrectal, Small organs, Urological, Transvaginal, Musculoskeletal.

VI. COMPARISON OF TECHNICAL CHARACTERISTICS

This device operates identically to the predicate devices in that the piezoelectric material in the transducer used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as images.

VII SAFETY AND EFFECTIVENESS

The Enovare is compliant to IEC 60601-1 Edition 3.1, International Electrotechnical Commission, Safety of Medical Electrical Equipment, Class II, Type B. Transducer is Type BF.

VIII BIOCOMATIBILITY

Enovare was tested in accordance with the testing requirements of the ISO 10993 recognized standards and found to be safe for its intended use.

IX CONCULUSION

The Enovare Ultrasound System is the same device as the predicate Sonalis system with additional added features found in the B&K Medical Flex Focus predicate. Otherwise the Enovare system also has updated components from the Sonalis that do not affect safety and efficacy. The Enovare has the same intended uses as found in the predicate devices and uses the same technological characteristics.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparison of Oreon Technologies Enovare to the Predicate Devices

	Enovare	**Sonalis** **K043189**	**B & K Medical Flex Focus 1202** **K123254**
1. Indications for use	General purpose ultrasound device for obtaining diagnostic medical images. Optional probes are available for general abdominal, small organ, gynecological, intraoperative, peripheral vascular muskulo skeletal and urological anatomy.	General purpose ultrasound device for obtaining diagnostic medical images. Optional probes are available for general abdominal, small organ, gynecological and urological anatomy.	Abdominal, Cardiac, Fetal, Intraoperative, Transurethral, Neurosurgery, Pediatrics, Transrectal, Small Parts, Transvaginal, Peripheral Vascular, Muskulo-skeletal
2. Scan Modes	B, PWD, CFM and combinations, Tissue Harmonic Imaging	Full Screen 2-D, Four Quadrant B-mode, B-mode, B-mode.	B, M, PWD, CFM and combinations, Tissue Harmonic Imaging
3. Transducers	Peripheral Vascular Endo-Rectal Intraoperative	Peripheral Vascular Endo-Rectal	Peripheral Vascular Endo-Rectal Intraoperative
4. Acoustic Output	All transducers are within Track III requirements.	All transducers are within Track I requirements.	1. All transducers are within Track III requirements.
5. Biometric Measurements	Same as Sonalis predicate. See page 12 of the system's User's Manual included in Section 4 of this submission.	Distance 6% - 14% Area 10% Ellipse 6 % - 23%	

Comparison of Oreon Technologies Enovare to the Predicate Device

	Enovare	Sonalis K043189	B & K Medical Flex Focus 1202 K123254
6. Thermal, Mechanical, and Electrical Safety	Designed to comply with IEC 60601-1 Edition 3.1, and/or prior editions.	IEC 60601-1-2	IEC 60601-1-2
7. Patient Contact Materials	The materials of construction of the patient contact portions of probes, components or accessories are identical to those used in similar probes, components or accessories of the Sonalis System and other predicate ultrasound systems.	The materials of construction of the patient contact portions of 5 probes, components or accessories are identical to those used in similar probes, components or accessories of the Sonada predicate ultrasound system.	
8. Cleaning, Disinfection, Sterilization	Cleaning and disinfection are the same as with the predicate Sonalis, and is described on page 40 of the user's manual. Sterilization is by Steris, the same as the B&K predicate and is described on page 41 of the user's manual.	Cleaning and disinfection is by industry standard methods described the user's manual.	Sterilization by Steris.