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

May 2, 2016

KOELIS
% Mrs. Laetitia Gervais
Quality and Regulatory Affairs Manager
5 Avenue du Grand Sablon
La Tronche 38700
FRANCE

Re: K160357
Trade/Device Name: TRINITY
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, LLZ
Dated: April 13, 2016
Received: April 18, 2016

Dear Ms. Gervais:

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,

For

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)*
K160357

Device Name
TRINITY

Indications for Use *(Describe)*
TRINITY® Ultrasound and Medical Imaging Processing System is intended to be used by clinicians and their assistants.
The device is indicated to generate, visualize and record 2D and 3D ultrasound images.
In the particular context of prostate biopsy, the device embedding the 3D PROSTATE SUITE SOFTWARE is indicated to process, visualize and record 3D digital ultrasound images in a view to map the organ.
Additional features include 2D/3D image and organ display, measurement, data management, multimodal image fusion (ultrasound, MRI, etc.).
Patient population: all patients requiring an ultrasound scan or ultrasound-based intervention particularly in urology.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) number : K160357

ANNEX: INDICATIONS FOR USE TABLES (FOUND IN SECTION 14)

The indications with clinical applications and exam types along with the modes of operation for TRINITY are recorded in the following tables.
Combinations identified "P" for the probes represents those previously cleared with this or another KOELIS Ultrasound system and those identified and "N" are new.

TRINITY

System: TRINITY

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

Clinical Application	Mode of Operation		
	B [4]	B+Color Doppler* [6]	Other (*Notes*)
Ophtalmic			
Fetal			
Abdominal *[1]*	N	N	
Intra-operative (Specify)			
Intra-operative (Neuro)			
Laparoscopic			
Pediatric			
Small Organ *[2]*	N	N	
Neonatal Cephalic			
Adult Cephalic			
Transrectal	N	N	*[5]*
Trans-vaginal	N	N	
Trans-urethral			
Trans-esoph. (non-Card.)			
Musculo-skeletal (**Conventional**)	N	N	
Musculo-skeletal (**Superficial**)	N	N	
Intravascular			
Other *[3]*	N	N	*[5]*
Cardiac Adult			
Cardiac Pediatric			
Intravascular (Cardiac)			
Trans-esoph. (Cardiac)			
Intra-cardiac			
Other			

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Clinical Application	Mode of Operation		
	B [4]	B+Color Doppler* [6]	Other (*Notes*)
Peripheral vessel			
Other			

** Color Doppler (CFM)*

NOTE

N = New indication; P =previously cleared by the FDA

[1] Abdominal includes for instance in urology kidneys and bladder

[2] Small organ includes for instance in urology scrotum and testicles

[3] Other use includes Urology / Prostate

[4] Includes volume-swept 3D B-Mode imaging

[5] Needle guidance imaging

[6] Combined modes are B+Color Doppler

2D LINEAR PROBE (K2DLN00)

System: TRINITY

Probe: 2D Linear probe (K2DLN00)

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

Clinical Application	Mode of Operation		
	B	B+Color Doppler*	Other (*Notes*)
Ophtalmic			
Fetal			
Abdominal *[1]*			
Intra-operative (Specify)			
Intra-operative (Neuro)			
Laparoscopic			
Pediatric			
Small Organ *[2]*	N	N	
Neonatal Cephalic			
Adult Cephalic			
Transrectal			
Trans-vaginal			
Trans-urethral			
Trans-esoph. (non-Card.)			
Musculo-skeletal **(Conventional)**	N	N	
Musculo-skeletal **(Superficial)**	N	N	

510(k) number : K160357

Clinical Application	Mode of Operation		
	B	B+Color Doppler*	Other (*Notes*)
Intravascular			
Other *[3]*			
Cardiac Adult			
Cardiac Pediatric			
Intravascular (Cardiac)			
Trans-esoph. (Cardiac)			
Intra-cardiac			
Other			
Peripheral vessel			
Other			

** Color Doppler (CFM)*

NOTE

N = New indication; P =previously cleared by FDA

[1] Abdominal includes for instance in urology kidneys and bladder

[2] Small organ includes for instance in urology scrotum and testicles

[3] Other use includes Urology / Prostate

2D ABDOMINAL PROBE (K2DAB00)

System: TRINITY

Probe: 2D abdominal probe (K2DAB00)

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

Clinical Application	Mode of Operation		
	B	B+Color Doppler*	Other (*Notes*)
Ophtalmic			
Fetal			
Abdominal *[1]*	N	N	
Intra-operative (Specify)			
Intra-operative (Neuro)			
Laparoscopic			
Pediatric			
Small Organ *[2]*			
Neonatal Cephalic			

5 510(K) SUMMARY OR 510(K) STATEMENT

510(k) Summary for TRINITY

The 510(k) summary is submitted in accordance with the requirements of.

510(k) Owner	KOELIS 5 avenue du Grand Sablon 38700 La Tronche FRANCE Phone: +33 476 637 587 Fax: +33 476 549 561
Contact Name:	Ms Laetitia GERVAIS Quality and Regulatory Affairs Manager Mail: gervais@koelis.com Phone: +33 476 637 587 Fax: +33 476 549 561
Date Prepared	February 1st, 2016

Proposed Device:

Trade Name	TRINITY
Common Name	Ultrasound and Medical Imaging Processing System
Classification Name	Ultrasonic Pulsed Doppler Imaging System (21CFR 892.1550) Ultrasonic Pulsed Echo Imaging System (21CFR 892.1560) Diagnostic Ultrasound Probe (21CFR 892.1570) System, Image processing, Radiological - Picture archiving and communication system -21CFR 892.2050)
Device Class	Class II
Product Code	IYN (21CFR 892.1550) IYO (21CFR 892.1560) ITX (21CFR 892.1570) LLZ (21CFR 892.2050)

Cleared Device:

The device is substantially equivalent to:

510(k) Number	Device Name
K141261 K131448	LOGIQ S7 Expert and LOGIQ S7 Pro (GE Healthcare) UROSTATION - 3D PROSTATE SUITE (KOELIS)

Intended Use:

TRINITY® Ultrasound and Medical Imaging Processing System and its probes are intended for diagnostic ultrasound imaging and analysis of fluids from the human body.

It is intended to be used by clinicians who are qualified to perform ultrasound diagnoses, in a clinical setting.

TRINITY® has been optimized for use in urological applications: Abdominal (kidneys, bladder, etc.), Small Organs (scrotum, testicles, etc.), Endocavity (prostate, etc.).

Indications for Use:

TRINITY® Ultrasound and Medical Imaging Processing System is intended to be used by clinicians and their assistants.
The device is indicated to generate, visualize and record 2D and 3D ultrasound images.
In the particular context of prostate biopsy, the device embedding the 3D PROSTATE SUITE SOFTWARE is indicated to process, visualize and record 3D digital ultrasound images in a view to map the organ.
Additional features include 2D/3D image and organ display, measurement, data management, multimodal image fusion (ultrasound, MRI, etc.).
Patient population: all patients requiring an ultrasound scan or ultrasound-based intervention particularly in urology.

Device Description:

TRINITY is an electro medical system considered as a system composed of:

- A mobile workstation composed by a central unit with ultrasound beamformer, a tactile screen, a mouse, a touch pen and a footswitch. All these components are assembled on a mobile cart. Optionally a keyboard can be delivered and a trackball mouse can be delivered instead of the mouse.
- Ultrasonic probe: 2D/3D end-fire endocavity probe. Optionally 2D probes can be delivered: linear probe and abdominal probe.
- 3D PROSTATE SUITE PROMAP software composed of the base software and PROMAP –Ty that drives the ultrasound module and perform additional measuring functions.

The system generates ultrasound waves in the low megahertz range, typically from 1 Mhz to 20 Mhz.

Two main ultrasound modes are provided by the system: ***B-mode imaging*** for structural analysis and ***Doppler imaging*** for body fluid flow analysis.

- B-mode imaging measures the time and waveform differences between wave emission and wave reception to reconstruct an image.
- Doppler imaging uses in addition the Doppler Effect to show flow direction and to inform about relative velocity (no measurement).

The system also provides ***3D B-mode imaging*** for high quality ultrasound acquisition of anatomical volumes. The technology employed is volume-swept 3D ultrasound.

The clinician can control acoustic output intensity with the ***TI*** *and* ***MI indices*** provided by the system. They indicate the level of thermal and mechanical stress that the system causes to the tissues, allowing the clinician to apply an ALARA-principle based exposure reduction strategy.

Technological Characteristics compared with the cleared device:

TRINITY employs the same fundamental scientific technology as its predicate devices.

TRINITY is substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- TRINITY and predicate TRINITY system have the same clinical intended use (TRINITY has less clinical intended use than its predicate).
- TRINITY and predicate TRINITY systems have the same imaging modes.
- TRINITY and predicate TRINITY systems probes are identical.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- TRINITY and predicate TRINITY systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- TRINITY integrates the software UROSTATION 3D PROSTATE SUITE (predicate K131448), which is intended to process, visualize and record 3D digital ultrasound images of the prostate.
- TRINITY and predicate systems have been designed in compliance with approved electrical and physical safety standards.

Summary of Non-Clinical Tests

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to compliant with applicable medical device safety standards. TRINITY and its applications comply with voluntary standards:

1. AAMI/ANSI ES60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety

2. IEC60601-1-2, Medical Electrical Equipment - Part I - 2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests

3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment

4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing

6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

7. ISO14971, Application of risk management to medical devices: Second edition

8. NEMA Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Probe materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission did not require clinical studies to support substantial equivalence.

Conclusion:

KOELIS considers TRINITY to be as safe, as effective, and performance is substantially equivalent to the predicate devices.