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

KOELIS
% Mrs. Laetitia Gervais
Quality and Regulatory Affairs Manager
16, chemin du Vieux Chêne
Meylan 38240
FRANCE

May 30, 2017

Re: K170521
Trade/Device Name: TRINITY/3D PROSTATE SUITE
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, LLZ
Dated: April 25, 2017
Received: April 27, 2017

Dear Mrs. 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)*
K170521

Device Name
TRINITY / 3D PROSTATE SUITE

Indications for Use *(Describe)*
Ultrasound System
TRINITY and its embedded 3D PROSTATE SUITE software are intended to be used by clinicians and their assistants, qualified to perform ultrasound diagnosis and ultrasound-guided procedures, in public or private hospitals.

TRINITY is indicated to:
• Generate ultrasound images for structural analysis and fluid flow analysis for
o urology,
o gynecology,
o vascular,
o abdominal,
o small organs,
o soft tissues and
o musculoskeletal
exams

TRINITY is not indicated for ophthalmic and cranial ultrasonography.

Medical Imaging Processing System
3D-PROSTATE SUITE, embedded on TRINITY or other KOELIS systems that do not integrate a 3D ultrasound module, is indicated to:
• Process, visualize and record various 2D and 3D image modalities (such as Ultrasound images, MRI)
• Fuse images of various modalities
• Display organ and perform measurements
• Display cartographies of prostate interventions (instrument positions)
• Manage patient data
• Import and export of data and images

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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"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."

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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]*	P	P	
Intra-operative (Specify)			
Intra-operative (Neuro)			
Laparoscopic			
Pediatric			
Small Organ *[2]*	P	P	
Neonatal Cephalic			
Adult Cephalic			
Transrectal	P	P	*[5]*
Trans-vaginal	P	P	
Trans-urethral			
Trans-esoph. (non-Card.)			
Musculo-skeletal (**Conventional**)	P	P	
Musculo-skeletal (**Superficial**)	P	P	
Intravascular			
Other *[3]*	P	P	*[5]*
Cardiac Adult			
Cardiac Pediatric			
Intravascular (Cardiac)			
Trans-esoph. (Cardiac)			
Intra-cardiac			
Other			
Peripheral vessel	N	N	
Other			

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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]*	P	P	
Neonatal Cephalic			
Adult Cephalic			
Transrectal			
Trans-vaginal			
Trans-urethral			
Trans-esoph. (non-Card.)			
Musculo-skeletal (**Conventional**)	P	P	
Musculo-skeletal (**Superficial**)	P	P	
Intravascular			
Other *[3]*			
Cardiac Adult			
Cardiac Pediatric			
Intravascular (Cardiac)			
Trans-esoph. (Cardiac)			
Intra-cardiac			

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Clinical Application	Mode of Operation		
	B	B+Color Doppler	Other (*Notes*)
Other			
Peripheral vessel	N	N	
Other			

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]*	P	P	
Intra-operative (Specify)			
Intra-operative (Neuro)			
Laparoscopic			
Pediatric			
Small Organ *[2]*			
Neonatal Cephalic			
Adult Cephalic			
Transrectal			
Trans-vaginal			
Trans-urethral			
Trans-esoph. (non-Card.)			
Musculo-skeletal (**Conventional**)	N	N	
Musculo-skeletal (**Superficial**)	N	N	
Intravascular			
Other *[3]*			
Cardiac Adult			

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

NOTE
N = New indication; P =previoustly 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

3D END-FIRE ENDOCAVITY PROBE (K3DEC00 / K3DEC00-2)

System: TRINITY

Probe: 3D end-fire endocavity probe (K3DEC00 / K3DEC00-2)

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	Other (*Notes*)
Ophtalmic			
Fetal			
Abdominal *[1]*			
Intra-operative (Specify)			
Intra-operative (Neuro)			
Laparoscopic			
Pediatric			
Small Organ *[2]*			
Neonatal Cephalic			
Adult Cephalic			
Transrectal	P	P	*[5]*
Trans-vaginal	P	P	
Trans-urethral			
Trans-esoph. (non-Card.)			
Musculo-skeletal (**Conventional**)			
Musculo-skeletal (**Superficial**)			
Intravascular			

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Clinical Application	Mode of Operation		
	B [4]	B+Color Doppler	Other (*Notes*)
Other *[3]*	P	P	*[5]*
Cardiac Adult			
Cardiac Pediatric			
Intravascular (Cardiac)			
Trans-esoph. (Cardiac)			
Intra-cardiac			
Other			
Peripheral vessel			
Other			

NOTE

N = New indication; P =previoustly 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

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

[5] Needle guidance imaging

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3D SIDE-FIRE ENDOCAVITY PROBE (K3DEL00)

System: TRINITY

Probe: 3D side-fire endocavity probe (K3DEL00)

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	Other (*Notes*)
Ophtalmic			
Fetal			
Abdominal *[1]*			
Intra-operative (Specify)			
Intra-operative (Neuro)			
Laparoscopic			
Pediatric			
Small Organ *[2]*			
Neonatal Cephalic			
Adult Cephalic			
Transrectal	N	N	*[5]*
Trans-vaginal			
Trans-urethral			
Trans-esoph. (non-Card.)			
Musculo-skeletal (**Conventional**)			
Musculo-skeletal (**Superficial**)			
Intravascular			
Other *[3]*	N	N	*[5]*
Cardiac Adult			
Cardiac Pediatric			
Intravascular (Cardiac)			
Trans-esoph. (Cardiac)			
Intra-cardiac			
Other			
Peripheral vessel			
Other			

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

510(K) SUMMARY OR 510(K) STATEMENT

510(k) Summary for

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

510(k) Owner	KOELIS 16, chemin du vieux chêne 38240 Meylan FRANCE Phone: +33(0)4 58 17 68 10 Fax: +33(0)4 58 17 68 24
Contact Name:	Ms Laetitia GERVAIS Quality and Regulatory Affairs Manager Mail: gervais@koelis.com Phone: +33(0)4 58 17 68 10 Fax: +33(0)4 58 17 68 24
Date Prepared	February 16, 2017

Proposed Device:

Trade Name	TRINITY / 3D PROSTATE SUITE
Common Name	Ultrasound and Medical Imaging Processing System
Classification Name	Picture Archiving And Communications System Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic ultrasonic transducer
Device Class	Class II
Product Code	LLZ (21CFR 892.2050) IYN (21CFR 892.1550) IYO (21CFR 892.1560) ITX (21CFR 892.1570)

Cleared Device:

The TRINITY is substantially equivalent to:

510(k) Number	Device Name
K160357 K160182	TRINITY Logiq S7 expert

Intended Use:

The Ultrasound System and Medical Imaging Processing System embedding 3D PROSTATE SUITE software and associated probes are intended for ultrasound diagnosis, ultrasound guided procedures and to process, visualize and record various image modalities.

Indications for Use:

Ultrasound System

TRINITY and its embedded 3D PROSTATE SUITE software are intended to be used by clinicians and their assistants, qualified to perform ultrasound diagnosis and ultrasound-guided procedures, in public or private hospitals.

TRINITY is indicated to:

- Generate ultrasound images for structural analysis and fluid flow analysis for
  - urology,
  - gynecology,
  - vascular,
  - abdominal,
  - small organs,
  - soft tissues and
  - musculoskeletal

  exams

TRINITY is not indicated for ophthalmic and cranial ultrasonography.

Medical Imaging Processing System

3D-PROSTATE SUITE, embedded on TRINITY or other KOELIS systems that do not integrate a 3D ultrasound module, is indicated to:

- Process, visualize and record various 2D and 3D image modalities (such as Ultrasound images, MRI)
- Fuse images of various modalities
- Display organs and perform measurements
- Display cartographies of prostate interventions (instrument positions)
- Manage patient data
- Import and export of data and images

Patient population

All patients requiring an imaging exam (such as ultrasound scan exam) or an ultrasound-based intervention.

Contraindications

The ultrasound process system is not intended for the followings:

- Ophtalmic use or any use that would cause the acoustic beam to pass through the eye.
- Use in combination with high frequencies surgical devices
- Use with a defibrillator while parts of the products are still in contact with the patient
- Use when the atmosphere is oxygen enriched (>25%)
- Use when there is a risk of presence of flammable gas as anesthetic mix, oxygen or nitrous oxide, close to the machine, to its screen or to its central unit

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 assembled on a mobile cart. Options, as keyboard and trackball mouse, can be delivered.
- Ultrasonic probe: 2D/3D end-fire endocavity probe and/or 2D/3D side-fire endocavity probe. 2D probes can be optionally delivered.
- 3D PROSTATE SUITE software composed of the base software and PROMAP –Ty that drives the ultrasound module and performs 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*** (including color flow sub-mode and power sub-mode) 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) (color flow sub-mode) or to show flow strength (power sub-mode).

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 devices:

TRINITY is substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics, scientific backgrounds, safety and effectiveness. TRINITY and the predicate devices are intended for diagnostic and interventional ultrasound imaging.

TRINITY provides the same grayscale (B-Mode) and Color Doppler ultrasound imaging modes than its previous clearance K160357. The abdominal, linear and end-fire endocavity ultrasound probes of TRINITY are unchanged from its previous clearance K160357, the only difference consisting in a minor modification of one material of the enclosure of the end-fire endocavity probe. TRINITY generates, like its predicate devices, acoustic power levels that are below the applicable FDA limits. TRINITY has the same measurement, digital image capturing, reviewing and reporting capabilities than the previous clearance K160357.

The differences with respect to the previous clearance K160357 of the TRINITY system are the addition of a side-fire endocavity ultrasound probe. The embedded 3D PROSTATE SUITE software was updated to support this probe. The range of indications of use of TRINITY was extended to include gynecology, vascular, soft tissues and musculoskeletal, which are also indications of use of predicate K160182.

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.