DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 31, 2017

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

Re: K171040
Trade/Device Name: Reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) and STEADY PRO range
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: July 11, 2017
Received: July 14, 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,

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)*
K171040

Device Name
Reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) and STEADY PRO range

Indications for Use *(Describe)*
The reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) and STEADY PRO range are indicated for diagnosis and treatment for ultrasound-guided interventions.

1. Reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range)
The reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) are indicated for guiding needles during ultrasound-guided interventions for diagnosis and treatment.

1.a. CON-LEAD range and LIN-LEAD range
The guides from CON-LEAD range and LIN-LEAD range are indicated for guiding needles during percutaneous ultrasound-guided interventions for diagnosis and treatment.

1.b. PERINE range
The guides from the PERINE range are indicated for guiding needles during percutaneous ultrasound-guided interventions for diagnosis and treatment on adult males.

2. Steady Pro range
The Steady Pro range provides physician a tool for performing ultrasound-guided interventions with the use of an endocavity ultrasound transducer for adult males requiring prostate biopsy mapping and cancer treatment.

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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510(K) SUMMARY OR 510(K) STATEMENT

510(k) Summary

The 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Owner	KOELIS 16, chemin du vieux Chêne 38240 Meylan FRANCE Phone : +33 458 176 810 Fax : +33 458 176 824
Contact Name:	Ms Laetitia GERVAIS Quality and Regulatory Affairs Manager Mail : gervais@koelis.com Phone : +33 458 176 811 Fax : +33 458 176 824
Date Prepared	2017.07.10

Proposed Device:

Trade Name	Reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) and STEADY PRO range
Common Name	Reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) and STEADY PRO range
Classification Name	Diagnostic Ultrasonic Transducer
Device Class	II
Product Code	ITX

Cleared Device:

The devices of the reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) and STEADY PRO range are substantially equivalent to:

510(k) Number	Device Name
K093713	Ultrasound General Purpose Guidance System
K131161	AccuCARE™ product line

Intended Use:

The reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) and STEADY PRO range are intended to provide a fixed path for needle insertion during ultrasound-guided interventions. The path is aligned with the ultrasound scan plane for needle imaging during the procedure. The ultrasound system can visualize the prospective path (as an on-screen guideline) in the ultrasound image to help needle positioning.

Reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range)

The reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) are intended to provide a fixed path for needle insertion during ultrasound-guided interventions. The path is aligned with the ultrasound scan plane for needle imaging during the procedure. The ultrasound system can visualize the prospective path (as an on-screen guideline) in the ultrasound image to help needle positioning.

CON-LEAD range and LIN-LEAD range

The guides from CON-LEAD range and LIN-LEAD range are intended to guide a needle during ultrasound-guided interventions.

PERINE range

The guides from the PERINE range are intended to guide a needle during ultrasound-guided interventions.

Steady Pro range

The Steady Pro range is intended to reliably maintain the position of a transrectal ultrasound probe during ultrasound-guided interventions. Typical applications are biopsy or cancer treatment.

Indications for Use:

The reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) and STEADY PRO range are indicated for diagnosis and treatment for ultrasound-guided interventions.

Reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range)

The reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) are indicated for guiding needles during ultrasound-guided interventions for diagnosis and treatment.

CON-LEAD range and LIN-LEAD range

The guides from CON-LEAD range and LIN-LEAD range are indicated for guiding needles during percutaneous ultrasound-guided interventions for diagnosis and treatment.

PERINE range

The guides from the PERINE range are indicated for guiding needles during percutaneous ultrasound-guided interventions for diagnosis and treatment on adult males.

Steady Pro range

The STEADY PRO range provides physician a tool for performing ultrasound-guided interventions with the use of an endocavity ultrasound transducer for adult males requiring prostate biopsy mapping and cancer treatment.

Device Description:

CON-LEAD range and LIN-LEAD range

The guides from CON-LEAD range and LIN-LEAD range have an attachment system in which a perforated part is attached in order to place a needle. It is a system with removable parts (nails) to adapt to the different diameters of needles.

The guides from CON-LEAD range and LIN-LEAD range shall guide and align needles of 14 gauge to 20 gauge with the (central) imaging plane of an ultrasound transducer such that needle is visible in the ultrasound plane at all relevant depth. The guides are reusable medical devices.

It is delivered cleaned but not sterile.

PERINE range

The guides from the PERINE range have an attachment system in which a perforated part is attached in order to place a needle. For some applications, there is a system with removable parts (nails) to adapt to the different diameters of needles. There is a possibility to have a fix or a movable system depending on the guide chosen.

The guides from the PERINE range shall guide and align needles of 14 gauge to 20 gauge with the (central) imaging plane of an ultrasound transducer such that needle is visible in the ultrasound plane at all relevant depth. The guides are reusable medical devices.

It is delivered cleaned but not sterile.

Steady Pro range

The Steady Pro range is a system which holds a 2D/3D lateral-fire endocavitary or 2D/3D end-fire endocavitary ultrasound probe. It is an accessory of KOELIS systems.

The main functions of the Steady Pro range are:

- To move the probe freely inside the working space of the probe holder in unlocked state
- To maintain the probe in a specific position for an extended time when locked
- To provide 6 degrees of freedom (rotation + translation) for arm and probe positioning; more specifically, to provide 160 degrees of rotation around the principal axis of the probe for side-fire probes, and 340 degrees of rotation for end-fire probes,
- Easy to use: setup and operation, probe installation/dismantling, locking/unlocking the position,
- Sterilizable and cleanable, easy to cover and protect.

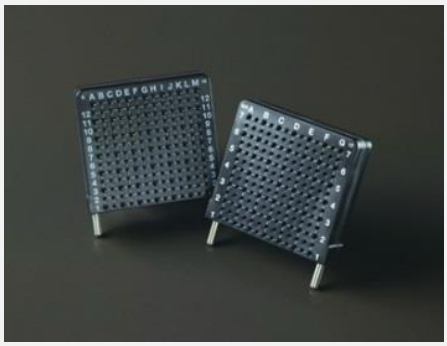
Technological Characteristics compared with the cleared device:

CON-LEAD range and LIN-LEAD range

Company	KOELIS	CIVCO
Devices	CON LEAD (abdominal guide) range  LIN LEAD (linear guide) range 	Ultrasound General Purpose Guidance:System (Ultra Pro II™) 
510(k) number	Unknown	K093713
Intended Use	The guides from CON-LEAD range and LIN-LEAD range are intended to guide a needle during ultrasound-guided interventions.	Intended for directing instruments such as catheters, electrodes and needles into a targeted anatomical location of a patient relative to the imaging instrument for percutaneous procedures. Intended for percutaneous ultrasound procedures
Design	Bracket adapted to the shape of the ultrasound transducer. Space to slide a nail in.	Bracket adapted to the shape of the ultrasound transducer. Space to slide a needle gauge insert in.
	Nail with an unchanging external diameter and with an internal diameter adapted to the needles.	Needle gauge insert with unchanging external dimensions and with an internal channel adapted to the instrument.

Company	KOELIS	CIVCO
Material	Propylux (polymer)	Materials not specified in IFU or website. Assumed to be a polymer.
Effectiveness	The design ensures accurate needle path and placement in relation with the transducer. Verification and validation were performed to ensure that devices meet requirements.	Verification was performed to ensure that device meets specified tolerances and works in conjunction with specifically designed adapter clip area.

PERINE guides

Company	KOELIS		CIVCO
Device	Perine Nail 	Perine Grid 	Disposable Template Grid 
510(k) number	Unknown		K131161
Intended Use	The guides from the PERINE range are intended to guide a needle during ultrasound-guided interventions.		Accepting and guiding needles up to 1.3 mm (18 gauge) in diameter and providing coordinates as an aid to needle loading and positioning during radioactive seed implantation, cryotherapy, transperineal template-guided biopsy, and/or fiducial marker placement. Intended for ultrasound percutaneous (including transperineal) procedures
Design	Clipping system to clip the guide on the probe.		Notch to fit on the stepping unit.
	Perine Nail : vertical grid with opened channels to slide a nail in. Perine Grid : vertical grid with closed channels to directly slide a needle in.		Square grid with closed channels to directly slide a needle/instrument in.
	Nail with an unchanging external diameter and with an internal diameter adapted to the needles.		-

Company	KOELIS	CIVCO
Material	Propylux (polymer)	ABS (polymer)
Effectiveness	The design ensures accurate needle path and placement in relation with the transducer. Verification and validation were performed to ensure that devices meet requirements.	Validation was conducted to confirm the device remains safe and effective for its intended use.

Steady Pro range

Company	KOELIS	CIVCO
Device	Steady Pro range 	Accucare™ micro-touch LP 
510(k) number	Unknown	K131161
Intended Use	Intended to reliably maintain the position of a transrectal ultrasound probe during ultrasound-guided interventions. Typical applications are biopsy or cancer treatment.	Holding and manipulating ultrasound imaging probes during prostate brachytherapy, cryotherapy, transperineal template-guided biopsy, and/or fiducial marker placement procedures (including volume determination of the prostate gland), and/or the application of radionuclide source(s) into the body during brachytherapy.
Design	Metallic holding arm with probe supports in polymer.	Metallic arm mounted on a table with a stabilizer
Material	Propylux (polymer) and stainless steel	Material is not specified in IFU or website. Assumed to be a metallic material.
Effectiveness	The design ensures accurate holding of the transducer. Verification and validation were performed to ensure that devices meet requirements.	Non-clinical performance testing was conducted including verification testing: Stepping Unit is able to provide continuous (free) longitudinal movement. Validation was also conducted to confirm the device remains safe and effective for its intended use.

Summary of Non-Clinical Tests

The devices from the reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) and STEADY PRO range have been evaluated for biocompatibility, cleaning and disinfection effectiveness and have been found to be compliant with applicable medical device safety standards. The devices and their applications comply with voluntary standards.

Summary of Clinical Tests

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

Conclusion:

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