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

510(k) Summary for REUSABLE GUIDE

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

510(k) Owner	KOELIS 5, avenue du Grand Sablon 38700 La Tronche FRANCE Phone: +33 476 637 588 Fax: +33 476 549.561
Contact Name:	Mrs Laetitia GERVAIS Quality Manager Mail: gervais@koelis.com
Date Prepared	2014.05.12

Proposed Device:

Trade Name	Reusable guide
Common Name	Ultrasound transducer needle/instrument guide
Classification Name	Ultrasonic Diagnostic Transducer accessories
Device Class	II
Product Code	ITX

Cleared Device:

The reusable guide is substantially equivalent to:

510(k) Number	Device Name
K875128/A	Transrectal Needle biopsy Guide

Intended Use:

The reusable guide is intended to provide physicians a tool for performing needle/instrument guided procedures with the use of the ultrasound endocavity transducer.
The guide is attached over the endocavity transducer/probe/scanhead instruments. This device provides a fixed path for the needle or the instrument that when coupled by the ultrasound system software corresponds to on-screen imaging guidelines for visualizing guided instrument placement procedures. KOELIS endorectal ultrasound guides are supplied cleaned and are reusable.

Indications for Use:

The reusable guide is dedicated for transrectal diagnosis ultrasound needle /instrument guided procedure.

Device Description:

The reusable guide is designed to be clipped onto an ultrasonic endocavity probe, to guide a needle along the said probe, and to be cleaned and re-sterilized after use.
The intended use and the indication for use place the Koelis reusable guide in device body contact category as follow :

Surface devices, intact sin/mucosal membranes limited contact (<24hours)

Technological Characteristics compared with the cleared device:

Substantial Equivalence Comparison Chart

Company	KOELIS	CIVCO
Device	Reusable guide	Transrectal Needle biopsy Guide
510(k) number	-	K875128/A
Intended Use	Both subject and predicate devices provide a mechanical means for performing transrectal needle/instrument guided procedures with the use of the diagnostic ultrasound endocavity transducer. The devices provide a fixed path for the needle or instrument that when coupled by the ultrasound system software corresponds to on-screen imaging guidelines for visualizing guided instrument placement procedures.	
	Intended for transrectal procedures	Intended for transrectal procedures
Design	Both subject and predicate devices include a linear tube with a stainless steel cannula attached external to the transducer at a fixed position.	
	An entry cone to easily introduce the needle into the tube	-
	Fixation mechanism of the guide on the probe : a clip welded on the tube, that allows the stability of the guide on the transducer and 2 fixing notches	a ring locks the guide around the probe thanks to a lateral screw.

Company	KOELIS	CIVCO
Device	Reusable guide	Transrectal Needle biopsy Guide
510(k) number	-	K875128/A
Material	Stainless steel 304 Stainless steel 316L Steel 17/4 PH These materials are widely used in medical applications for implants and ancillaries.	Stainless steel 304
Safety	As these materials are widely used, Koelis conducted a biological safety evaluation based on a risk-based analysis, the literature data and manufacturing process used according to ISO10993-1. The associated report concluded that these data were adequate to demonstrate the biological safety.	Biological safety has been evaluated using biocompatibility tests in accordance with ISO 10993-1. Testing has demonstrated t the biological safety of the device
Effectiveness	Both the subject and predicate devices are designed for secure and aligned fit to the transducer, while not altering the transducer design integrity or function. Positive registration features of the design ensures accurate needle / instrument path and placement in relation with the transducer. Exterior shapes of the guide are contoured for patient comfort with no sharp edges.	

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

July 11, 2014

KOELIS
% LAETITIA GERVAIS
QUALITY MANAGER
5 AVENUE DU GRAND SABLON
LA TRONCHE 38700
FRANCE

Re: K141334
Trade/Device Name: Reusable Guide
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: July 1, 2014
Received: July 2, 2014

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,

Michael D. O'Hara For

Janine M. Morris
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)*
Unknown K141334

Device Name
REUSABLE GUIDE

Indications for Use *(Describe)*
The reusable guide is dedicated for transrectal diagnosis ultrasound needle /instrument guided procedure.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Richard D. O'Hara

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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