KOELIS
% Ms. Pauline Nicole
Regulatory Affairs Engineer
16, chemin du vieux chêne
Meylan, Isere 38240
FRANCE

July 10, 2018

Re: K180970
Trade/Device Name: Disposable Guide KDNG00
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: June 13, 2018
Received: June 18, 2018

Dear Ms. Nicole:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180970

Device Name
Disposable guide KDNG00

Indications for Use *(Describe)*
The disposable guide KDNG00 is dedicated for endocavity diagnosis ultrasound needle guided procedure. It is intended for clinicians and assistant clinicians, in clinic and hospital, to guide linear instrument with a transrectal approach.

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 for Disposable Guide KDNG00

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(0)4 58 17 68 10 Fax : +33(0)4 58 17 68 24
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Date Prepared	2018.06.12

Proposed Device

Trade Name	Disposable Guide KDNG00
Common Name	Disposable Guide KDNG00
Classification Name	Ultrasound Diagnostic Transducer Accessories
Device Class	II
Product Code	ITX

Cleared Device

The disposable guide KDNG00 is substantially equivalent to:

510(k) Number	Device Name
K141334	Reusable Guide (primary predicate device)
K970514	Transrectal Needle Biopsy Guide (reference device)

Intended Use of the subject device

The disposable guide KDNG00 provides a fixed path for the needle that when coupled by the ultrasound system software corresponds to on-screen imaging guidelines for visualizing guided instrument placement procedures.

Indications for Use of the subject device

The disposable guide KDNG00 is dedicated for endocavity diagnosis ultrasound needle guided procedure. It is intended for clinicians and assistant clinicians, in clinic and hospital, to guide linear instrument with a transrectal approach.

Subject device description

The products concerned are plastic guides designed to be clipped on an endocavity ultrasound probe (KOELIS probes K3DEC00/K3DEC00-2 cleared under K170521), to guide a linear instrument through transrectal access.

The disposable guides KDNG00 are packaged individually in pouches and delivered sterile. Pouches are then gathered in dispenser boxes (24 guides/dispenser box).

Technological Characteristics compared with the cleared device

Company	KOELIS	KOELIS	CIVCO
Device	Disposable guide KDNG00	Reusable guide	Transrectal Needle Biopsy Guide
510(k) Number	Unknown	K141334	K970514
Intended Use	Both subject and predicate devices provide a mechanical means for performing transrectal needle guided procedures with the use of the diagnostic ultrasound endocavity transducer. The devices provide a fixed path for the needle that when coupled by the ultrasound system software corresponds to on-screen imaging guidelines for visualizing guided instrument placement procedures.		
	Intended for transrectal procedures		
Design	Plastic guide designed to be clipped on an endocavity ultrasound pobe. An entry cone to easily introduce the needle into the tube.	Inox guide designed to be clipped on an endocavity ultrasound pobe. An entry cone to easily introduce the needle into the tube.	Integrates the mounting bracket and cannula into a single, disposable component that attaches externally, over the transducer with a clip-on action.
	Fixation mechanism of the guide on the probe :		
	A clip to allow the guide stability on the transducer, and 2 pins for attachment in the notches of the probe.	A clip to allow the guide stability on the transducer, and 2 pins for attachment in the notches of the probe.	A ring locks the guide around the probe thanks to a lateral screw.
Material	Polycarbonate, medical grade	Stainless steel 304 Stainless steel 316L Steel 17/4 PH	Thermoplastics (ABS, polycarbonate) and stainless steel (T304 Hypodermic grade tubing)
Safety	Biological safety has been evaluated using biocompatibility tests for cytotoxicity, irritation and sensitization in accordance with ISO	As the reusable guide's materials are widely used, Koelis conducted a biological safety evaluation based on a risk-based analysis, the literature	Testing is in accordance with ISO 10993-1, FDA Blue Book Memorandum #G95-1 and FDA Good

Company	KOELIS	KOELIS	CIVCO
Device	Disposable guide KDNG00	Reusable guide	Transrectal Needle Biopsy Guide
510(k) Number	Unknown	K141334	K970514
	10993-1 and FDA Good Laboratory Practices (GLP). Biocompatibility testing has demonstrated that the disposable guide KDNG00 is biologically safe as it has no cytotoxic, irritation or sensitization effects. The tests have been conducted on sterile disposable guides. The EtO sterilization procedure has been tested according to ISO 11135-1. The associated report concluded that these data were adequate to demonstrate the biological safety.	data and manufacturing process used, according to ISO 10993-1.	Laboratory Practices (GLP). Materials and manufacturing processing (including EtO sterilization) have been biologically evaluated using biocompatibility tests for cytotoxicity, irritation and sensitization. Testing has demonstrated device to be non-toxic, non-sensitizing and non-irritating. Biocompatibility testing was conducted using sterilized finished devices.
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 path and placement in relation with the transducer. Exterior shapes of the guide are contoured for patient comfort with no sharp edges.		

Summary of non-clinical testing

The disposable guides KDNG00 has been evaluated for biocompatibility and sterilization effectiveness, and has been found to be compliant with applicable medical device safety standards. The disposable guide KDNG00 and its applications comply with voluntary standards.

Summary of clinical testing

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

Conclusion

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