November 14, 2023

CIVCO Medical Instruments Co., Inc.
% James Leong
Regulatory Affairs Manager
102 First Street South
KALONA IA 52247

Re: K231783
Trade/Device Name: VitroPRO
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX, MQE
Dated: November 7, 2023
Received: November 7, 2023

Dear James Leong:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna S. Kang -S

Yanna Kang
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231783

Device Name

VitroPRO

Indications for Use *(Describe)*

This device provides physicians with a tool for performing needle/instrument guided procedures with the use of diagnostic ultrasound endocavity transducers.

• Transvaginal - Diagnostic ultrasound needle / instrument guided procedures such as tissue biopsy, fluid aspiration, catheter placement, treatment, and oocyte retrieval.
• Transrectal - Diagnostic ultrasound needle / instrument guided procedures such as tissue biopsy, fluid aspiration, catheter placement, 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.

510(k) Summary

This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K231783

1. Submitter's Identifications:

Establishment:	CIVCO Medical Instruments Co., Inc.
Address:	102 First Street South Kalona, IA 52247
Registration Number:	1937223
Operations Manufacturer Owner/Operator:	CIVCO Medical Instruments Co., Inc.
Owner/Operator Number:	1937223
Contact Person:	Jim Leong
Phone:	319-248-6502
e-mail:	James.Leong@civco.com

2. Date 510(k) Summary Prepared: June 12, 2023

3. Name of the Subject Device and Classification Information:

Trade/Device Name	VitroPRO
Regulation Number	21 CFR 892.1570
Classification Name	Diagnostic ultrasonic transducer Assisted reproduction needles
Regulatory Class	Class II
Product Code	ITX & MQE

4. Information for the Predicate Device:

Tradename/Device Name	VitroPRO
Manufacturer	CIVCO Medical Instruments Co., Inc.
510(k) Number	K222052
Regulation Number	892.1570
Classification Name	Diagnostic ultrasonic transducer
Regulatory Class	II
Product Code	ITX & MQE

5. Device Description:

The VitroPRO disposable endocavity needle guides are devices used to direct needles or instruments along a fixed path to a target location with an ultrasound traducer. They are provided in a variety of sizes to fit different equipment and situations. They can be utilized for various types of procedures from tissue biopsy and fluid aspirations to instrument placements and oocyte harvesting.

6. Intended Use / Indications for Use:

This device provides physicians with a tool for performing needle/instrument guided procedures with the use of diagnostic ultrasound endocavity transducers.

- Transvaginal - Diagnostic ultrasound needle / instrument guided procedures such as tissue biopsy, fluid aspiration, catheter placement, treatment, and oocyte retrieval.

- Transrectal - Diagnostic ultrasound needle / instrument guided procedures such as tissue biopsy, fluid aspiration, catheter placement, treatment.

7. Comparison to Legally Marketed Device

Item	Subject Device VitroPRO Disposable Endocavity Needle Guide K23XXXX	Predicate Device VitroPRO Disposable Endocavity Needle Guide K222052
Material	Same	ABS Thermoplastic
	Cannula: Same	Cannula: Stainless Steel
Biocompatibility	Same	Meets ISO 10993-1 biocompatibility requirements for limited contact duration: • surface devices of breached or compromised surface • External communicating indirect blood path/tissue contact Demonstrated to be non-toxic, non-sensitizing, non-irritating, non-hemolytic, and non-

Item	Subject Device VitroPRO Disposable Endocavity Needle Guide K23XXXX	Predicate Device VitroPRO Disposable Endocavity Needle Guide K222052
		pyrogenic
Mouse Embryo Assay (MEA)	Demonstrated to be non-toxic for exposure to embryo development.	N/A
Limulus Amebocyte Lysate (LAL)	Demonstrated to be within accepted specification for endotoxin units for exposure.	N/A
Sterilization	Same	Ethylene Oxide
Shelf-life	Same	3 years
Accessory	Same	None provided.

8. Comparison of Indications to the Legally Marketed Device:

The proposed endocavity needle guides have the same intended use and indications for use. The labeling has been updated to add additional claims for use for use with oocyte retrieval. The addition to the labeling would not affect the safety or effectiveness of the device. Any questions related to compliance to the expanded labeling claims safety and effectiveness of the endocavity guides have been addressed using the testing provided showing devices meet acceptance criteria for mouse embryo assay (MEA) and limulus amobocyte lysate (LAL) tests.

9. Summary of Non-Clinical Tests Performed:

The disposable endocavity needle guides devices met acceptance threshold requirements and show passing results to the following testing performed:

- Mouse Embryo Assay (MEA) - One-cell mouse embryos were incubated in extracts of the subject device and cultured at 37 °C. The percent of embryos developed to the expanded blastocyst stage within 96-hours was assessed in comparison to the control group. The acceptance criterion for the 1-Cell MEA was ≥80% embryos expanded to blastocyst at 96 hours.
- Limulus Amebocyte Lysate (LAL) testing per USP 161. The acceptance criterion was ≤ 20 EU/device.

10. Conclusions:

The disposable endocavity needle guide devices have the same intended use and its technological characteristics do not raise any different questions of safety or effectiveness, as compared to the legally marketed device. The addition of oocyte harvesting to the indications for use have been tested to show the devices are safe for such usage. Therefore, the endocvity

needle guides are substantially equivalent to the legally marketed disposable endocavity needle guide devices marketed by CIVCO.