November 22, 2022

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

Re: K222052
Trade/Device Name: VitroPRO
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX, MQE
Dated: October 14, 2022
Received: October 24, 2022

Dear Jim 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 (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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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, Ph. D.
Assistant Director
Mammography and Ultrasound Team
DHT 8C: 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.

510(k) Number *(if known)*

K222052

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.

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.

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Appendix A – 510(k) Summary

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: K222052 .

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: July 5, 2022

3. Name of the Subject Device and Classification Information:

Trade/Device Name	VitroPRO / Disposable Endocavity Needle Guide
Regulation Number	21 CFR 892.1570 21 CFR 884.6100
Classification Name	Diagnostic ultrasonic transducer Assisted reproduction needles Class II
Regulatory Class	ITX & MQE
Product Code	

4. Information for the Predicate Device:

Tradename/Device Name	Disposable Endocavity Needle / Biopsy Guide
Manufacturer	CIVCO Medical Instruments Co., Inc.
510(k) Number	K970514
Regulation Number	892.1570
Classification Name	Diagnostic ultrasonic transducer
Regulatory Class	II
Product Code	ITX

5. Information for Reference Device:

Tradename/Device Name	Embryon® Ultrasound Needle Guides
Manufacturer	Rocket Medical PLC
510(k) Number	K032015
Regulation Number	884.6100 892.1560
Classification Name	Diagnostic ultrasonic transducer
Regulatory Class	II
Product Code	MQE & IYO

6. Device Description:

The 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.

7. 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.

8. Comparison to Legally Marketed Device

Item	Subject Device CIVCO Disposable Endocavity Needle Guide K21XXXX	Predicate Device CIVCO Disposable Endocavity Ultrasound Needle / Biopsy Guide K970514
Material	ABS Thermoplastic	ABS Thermoplastic
	Cannula: Stainless Steel	Cannula: Stainless Steel

Item	Subject Device CIVCO Disposable Endocavity Needle Guide K21XXXX	Predicate Device CIVCO Disposable Endocavity Ultrasound Needle / Biopsy Guide K970514
	All materials have met the requirements of ISO 10993-1 for biocompatibility.	All materials have met the requirements of ISO 10993-1 for biocompatibility.
Biocompatibility	Meets ISO 10993-1 biocompatibility requirements for limited contact duration: • surface devices of breached or compromised surface • Externally communicating tissue bone/dentin Demonstrated to be non-toxic, non-sensitizing, non-irritating, (not labeled non-pyrogenic)	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-pyrogenic
Sterilization	Ethylene Oxide	Ethylene Oxide
Shelf-life	3 years	3 years
Accessory	None provided. Intended user to provide cover and guides which are IVF use cleared.	Ultrasound gel packet and covers.

9. Comparison of Indications to the Legally Marketed Device:

The proposed endocavity needle guides have the same intended use. The language used has been updated for clarity and to add an additional indication for use for oocyte retrieval. The differences in the indications for use statement would not affect the safety or effectiveness of the device because the safety and efficacy related to the indicated procedures is dictated by the use of the underlying ultrasound equipment. Any questions related to safety and effectiveness of the endocavity guides have been addressed using the same testing performed by the legally marketed device, including updated biocompatibility evaluations.

10. Summary of Non-Clinical Tests Performed:

- Biocompatibility:

  The disposable endocavity needle guides devices met ISO 10993-1 biocompatibility requirements for limited contact duration for surface devices of breached or compromised surface and external communicating tissue/bone/dentin contact:

  - Cytotoxicity – ISO 10993-5
  - Sensitization – ISO 10993-10
  - Irritation – ISO 10993-10

- Cover breach and probe damage testing

  Water leak testing was performed to demonstrate material attachment of needle guide to over a cover did not cause damage to cover or probe.

- Retention and movement testing

  Force testing was performed on needle guide attachment to ensure a minimum force of 8N would not cause the guide to dislodge.

- Needle drag testing

  Force testing was performed by passing a cannula through the needle guide to ensure binding would not occur and force was less than a 1.5N threshold.

- Needle path verification testing

  Needle guides were tested on test fixtures to ensure needle path falls within the design tolerances specified for the design.

- Simulated Usability Testing

  Simulated use evaluations were performed by customers to ensure the design of the needle guide conforms to the user needs and intended use.

11. Clinical Test Performed:

Clinical tests were not required to demonstrate substantial equivalence.

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