July 1, 2024

CIVCO Medical Solutions
James Leong
Regulatory Affairs Manager
102 First Street South
Kalona, Iowa 52247

Re: K233109
Trade/Device Name: TP Pivot Pro™ Needle Guide
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX

Dear James Leong:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on December 22, 2023. Specifically, FDA is updating this SE Letter because FDA inadvertently indicated that the SE determination also included review and clearance of a predetermined change control plan (PCCP). However, your 510(k) submission did not include a PCCP, so FDA is providing this administrative correction. Please see the attached revised clearance letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yanna Kang, OHT8: Office of Radiological Health, (301)796-6704, Yanna.Kang@fda.hhs.gov.

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
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

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Trade/Device Name: TP Pivot Pro™ Needle Guide
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX
Dated: September 25, 2023
Received: September 27, 2023

Dear James Leong:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on December 22, 2023.

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, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
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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)*

K233109

Device Name

TP Pivot Pro™ Needle Guide

Indications for Use *(Describe)*

Device is intended to be used for instrument placement to access anatomical structures under transrectal ultrasound guidance.

- Prostate - Biopsy and minimally invasive puncture.
- Surgical (Prostate)- Biopsy and minimally invasive puncture.

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary is prepared in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K233109 .

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: September 25, 2023

3. Name of the Subject Device and Classification Information:

Trade/Device Name	TP Pivot Pro™ Needle Guide
Regulation Number	21 CFR 892.1570
Classification Name	Diagnostic ultrasonic transducer
Regulatory Class	Class II
Product Code	ITX

4. Information for the Predicate Device:

Tradename/Device Name	PrecisionPoint Biopsy Needle Guide
Manufacturer	Corbin Clinical Resources, LLC
510(k) Number	K160414
Regulation Number	892.1570
Classification Name	Diagnostic ultrasonic transducer
Regulatory Class	Class II
Product Code	ITX

5. Device Description:

The TP Pivot Pro™ needle guide is a tool for performing freehanded transperineal prostate biopsies, taking advantage of the transperineal path to sample regions of the prostate including the difficult to reach anterior zone. Used in conjunction with an ultrasound probe, users visualize suspect target areas of the prostate, plan and position an access site, and obtain specimens from a precise point in the prostate.

6. Intended Use / Indications for Use:

Device is intended to be used for instrument placement to access anatomical structures under transrectal ultrasound guidance.

- Prostate – Biopsy and minimally invasive puncture
- Surgical (Prostate) – Biopsy and minimally invasive puncture

7. Comparison to Legally Marketed Device

Item	Subject Device TP Pivot Pro™ Needle Guide K233109	Predicate Device PrecisionPoint Needle Guide K160414
Material	ABS Thermoplastic	Polymeric material
	Introducer needle – 304 stainless steel	Introducer needle – 304 stainless steel
Biocompatibility	Meets ISO 10993-1 biocompatibility requirements for limited contact duration: • surface devices of breached or compromised surface • externally communicating tissue/bone/dentin	Meets ISO 10993-1 biocompatibility requirements for limited contact duration: • surface devices of breached or compromised surface
Sterilization	Ethylene Oxide	Ethylene Oxide
Shelf-life	1 year	3 years
Accessory	Optional NeoGuard transducer cover (K013721)	Users informed to use transducer cover

8. Comparison of Indications to the Legally Marketed Device:

The TP Pivot Pro™ needle guide has the same basic intended use as the predicate, which is to place needle into and anatomical structure using an ultrasound transducer. CIVCO has further added the following indications for use for the TP Pivot Pro™ needle guide which is not specifically called out in the predicate.

- Prostate – Biopsy and minimally invasive puncture
- Surgical (Prostate) – Biopsy and minimally invasive puncture

9. Summary of Non-Clinical Tests Performed:

- Biocompatibility:

  The TP Pivot Pro™ needle guide and accessories are manufactured with materials which meet ISO 10993-1 biocompatibility requirements for limited contact duration for surface devices of breached or compromised surface. These same materials are already utilized on CIVCO cleared medical devices for contact in the same regions.

  - Cytotoxicity – testing in accordance with ISO 10993-5
  - Sensitization – testing in accordance with ISO 10993-10
  - Irritation – testing in accordance with ISO 10993-10
  - Acute Systemic Toxicity – testing in accordance with ISO 10993-11
  - Material Mediated Pyrogen – testing in accordance with ISO 10993-11

- Design specification:

  The TP Pivot Pro™ needle guide and accessories have certain design functionality which was tested internally to verify they meet the established requirements. These criteria are listed as follows:

  - Guide Tangential Clocking force testing - This test confirms that the guide adequately attaches to the round probe such that it, once clamped, would not rotate around the probe in a typical use.
  - Guide Axial Loading force testing - This test confirms that the guide adequately attaches to the round probe such that it, once clamped, would not slide forward in a typical use.
  - Guide Dislodge Force Test - This test confirms that the guide adequately attaches to the round probe such that it, once clamped, would not dislodge when a force is applied to the worst-case location that is furthest from the areas where the guide attaches to the probe.
  - Needle Holder Force (horizontal) Test - This test confirms that the force to dislodge the needle holder from a clamped horizontal position shall be at the worst case position which is furthest from where the needle holder attaches to the guide.
  - Needle Holder Force (angled) Test - This test confirms that the force to dislodge needle holder from a clamped, angled position of approximately 20° shall and applied at the worst case position which is furthest from where the holder attaches to the guide.

- Assemble/Removal Force with Neoguard Cover Test – This tests the force required to assemble the guide onto or remove the guide from the simulated probe with a Neoguard cover.
- Guide Clamp Knob Torque Test - This test confirms that the guide is not damaged when the user applies torque to the guide clamp knob to attach probe.
- Extract/Insert Needle Holder in Tower Force - The force to extract/insert the needle holder from/into the guide tower.
- Introducer needle initial insertion force - The initial insertion force of the introducer needle into the needle holder.
- Introducer needle In and out of the needle holder force test - The force to move the introducer needle into or out of the needle holder.

- 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.

- Guidance Standards
  The introducer needle was evaluated against BS EN ISO 9626:1995 and believe it complies with the standard.

10. Clinical Test Performed:

Clinical tests were not required to demonstrate substantial equivalence.

11. Conclusions:

The TP Pivot Pro™ needle guide has the same intended use as compared to the legally marketed device. The design differences do not add any additional risk to the use of the device. Therefore, the TP Pivot Pro™ needle guide is substantially equivalent to the legally marketed PrecisionPoint needle guide marketed by Corbin Clinical Resources, LLC.