



September 24, 2026

CIVCO Medical Instruments Co., Inc.
James Leong
Regulatory Affairs
750 Lois Lane
Coralville, IA 52241

Re: K260114

Trade/Device Name: Align® Cover and Pad Guidance Tool
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX
Dated: August 26, 2026
Received: August 26, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

MARJAN NABILI -S for

Yanna Kang, Ph.D.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260114

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Please provide the device trade name(s).

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Align® Cover and Pad Guidance Tool

Please provide your Indications for Use below.

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The medical device is intended to provide a guide for interventional devices while also serving as a microbial barrier between the patient and the ultrasound transducer.

- Abdominal - Diagnostic imaging and minimally invasive puncture procedures.
- Small Parts - Diagnostic imaging and minimally invasive puncture procedures.
- Regional Anesthesia - Diagnostic imaging and minimally invasive puncture procedures.
- Vascular Access - Diagnostic imaging and minimally invasive puncture procedures.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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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: K260114

1. Submitter's Identifications:

Establishment:	CIVCO Medical Instruments Co., Inc.
Address:	750 Lois Lane Coralville, IA 52241
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: January 12, 2026

3. Name of the Subject Device and Classification Information:

Trade/Device Name	Align® Cover and Pad Guidance Tool
Regulation Number	21 CFR 892.1570
Classification Name	Diagnostic ultrasonic transducer
Regulatory Class	Class II
Product Code	ITX

4. Information for the Primary Predicate Device:

Tradename/Device Name	Envision™ Ultrasound Cover and Pad
Manufacturer	CIVCO Medical Instruments Co., Inc.
510(k) Number	K190802
Regulation Number	892.1570
Classification Name	Diagnostic ultrasonic transducer
Regulatory Class	Class II
Product Code	ITX

Information for the Secondary Predicate Device:

Tradename/Device Name	Ultrasound General Purpose Guidance System
Manufacturer	CIVCO Medical Instruments Co., Inc.
510(k) Number	K093713
Regulation Number	892.1570
Classification Name	Diagnostic ultrasonic transducer
Regulatory Class	Class II
Product Code	ITX

5. Device Description:

The Align® Cover and Pad Guidance Tool offers a unique approach to ultrasound-guided procedures by providing a guide that positions the interventional instrument in the field of view of the ultrasound beam, as well as a microbial barrier and ultrasound conductive medium between the patient and the ultrasound transducer.

6. Intended Use / Indications for Use:

The medical device is intended to provide a guide for interventional devices while also serving as a microbial barrier between the patient and the ultrasound transducer.

- Abdominal - Diagnostic imaging and minimally invasive puncture procedures.
- Small Parts - Diagnostic imaging and minimally invasive puncture procedures.
- Regional Anesthesia - Diagnostic imaging and minimally invasive puncture procedures
- Vascular Access - Diagnostic imaging and minimally invasive puncture procedures

7. Comparison to Legally Marketed Device

	Subject Device Align® Cover and Pad Guidance Tool	Primary Predicate Envision™ Ultrasound Cover and Pad- K190802	Secondary Predicate Ultrasound General Purpose Guidance System (Infiniti)- K093713
Materials			
• Pad	Polycarbonate, silicone elastomer, polyether polyurethane, coating formulation (Hydromer or Aculon) No-Tox Liquid Ink FGN-1636 NT21 Black	Polycarbonate, silicone elastomer, polyether polyurethane, coating formulation (Hydromer or Aculon)	N/A
• Cover	Polyurethane (and those in the pad)	Polyurethane (and those in the pad)	N/A

	Subject Device Align® Cover and Pad Guidance Tool	Primary Predicate Envision™ Ultrasound Cover and Pad- K190802	Secondary Predicate Ultrasound General Purpose Guidance System (Infiniti)- K093713
• Guide	Polypropylene Clariant Colorant OC5SAF (Pale Blue)	N/A	ABS
Microbial Barrier	Meets requirements of ASTM F1671-13 for prevention of blood- borne pathogens	Meets requirements of ASTM F1671-13 for prevention of blood- borne pathogens	N/A
Biocompatibility	Meets ISO 10993-1 Biocompatibility requirements for surface devices with limited (≤ 24 hours) contact with breached or compromised surface	Meets ISO 10993-1 biocompatibility requirements for limited (≤ 24 hours) contact duration: • surface devices in contact with breached or compromised surface • external communicating device with indirect contact with blood path/tissue	Meets ISO 10993-1 Biocompatibility requirements for limited (≤ 24 hours) contact duration for external communicating devices in contact with tissue/bone/dentin
Shelf Life	15 Months	3 years	3 years
Included Accessories	Sterile Saline Wipe Bands with cover configurations	Sterile Saline Wipe Bands with cover configurations	Probe Cover with gel and bands

8. Comparison of Indications to the Legally Marketed Device:

The proposed Align device has the same basic intended use as the predicate, which is to help direct interventional instruments into an anatomical structure using an ultrasound transducer. CIVCO has further combined the indications for use for the Envision Cover and Pad along with the Infiniti Needle Guide into bullet point format.

- Abdominal - Diagnostic imaging and minimally invasive puncture procedures.
- Small Parts - Diagnostic imaging and minimally invasive puncture procedures.
- Regional Anesthesia - Diagnostic imaging and minimally invasive puncture procedures
- Vascular Access - Diagnostic imaging and minimally invasive puncture procedures

9. Summary of Non-Clinical Tests Performed:

- Biocompatibility:

The Align® Cover and Pad Guidance Tool 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.

- Design specification:
The Align® Cover and Pad Guidance Tool have certain design functionality which was tested internally to verify they meet the established requirements. These criteria are listed as follows:
 - Visual Inspection testing - This test confirms that the device is assembled correctly, there is no exposed adhesive.
 - Dimensional testing - This test confirms that the guide is properly attached to the cover and pad.
 - Adhesive Force Test - This test confirms that the device will remain attached with a minimum amount of force.
 - Spring Force and Deflection Test - This test confirms that the force to deflect the instrument holder retaining tab can deflect with a minimum amount of force and return within 10 degrees of the original position.
 - Functional Scanning Test - This test confirms the pad and cover are compatible with ultrasound imaging equipment.
 - Cover Leak Test – This test ensures manufacturing produces covers without holes.
 - Pin Slip Test - This test confirms that the device can be utilized with instruments up to 18GA in size.
 - Rehydration Test – This test ensures the coating on the Align Covers and Pads is capable of being rehydrated multiple time during a procedure.
 - Tensile Strength Test – This testing confirmed that the device demonstrates the same material tensile strength as the predicate device.
 - Tear Resistance Test - This testing confirmed that the device demonstrates the same material tear resistance as the predicate device.
 - Air Burst Pressure and Volume Testing – This test confirms mechanical integrity of the covers.

- Simulated Usability Testing
Simulated use evaluations were performed by customers to ensure the design of the Align device conforms to the user needs and intended use.

10. Clinical Test Performed:

Clinical tests were not required to demonstrate substantial equivalence.

11. Conclusions:

Given that the subject and predicate devices have the same intended use and their technological characteristics achieve the same goal even though the designs are different, there is not a different question of safety and effectiveness. Therefore, the subject device is substantially equivalent to the primary predicate device.