



Food and Drug Administration
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Silver Spring, MD 20993-0002

Civco Medical Instruments Co., Inc.
% Ms. Amanda Stahle
Sr. Regulatory Affairs Specialist
102 First Street South
KALONA IA 52247

August 5, 2016

Re: K160806
Trade/Device Name: Verza™ Guidance System
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: July 27, 2016
Received: July 29, 2016

Dear Ms. Stahle:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Indications for Use

510(k) Number (if known)

K160806

Device Name

Verza Guidance System

Indications for Use (Describe)

The system provides guidance for precise instrument placement of common interventional devices by positioning the device relative to the ultrasound transducer and the resulting image during a diagnostic or therapeutic procedure. This guidance system is intended for use with pediatric and adult patients.

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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Section 5 – 510(k) Summary

A. Submitter Information

Submitter Name & Address: CIVCO Medical Instruments Co., Inc.
d/b/a CIVCO Medical Solutions
102 First Street South
Kalona, IA 52247

Contact Person: Amanda Stahle, Sr. Regulatory Affairs Specialist
Telephone: 319-248-6628, Fax: 877-218-0324
amanda.stahle@civco.com

Date Summary Prepared: March 21, 2016

Trade Name: Verza™ Guidance System
Common Name: Ultrasound General Purpose Guidance System
Classification Name & Number: Diagnostic ultrasonic transducer (892.1570)
Device Class: Class II
Review Panels: Radiology
Product Codes: ITX

B. Predicate Device

The proposed guidance system is substantially equivalent to the following predicate guidance system:

Predicate Device	Manufacturer
NEEDLE GUIDE FOR 8814, MODEL UA1335, NEEDLE GUIDE FOR 8815, MODEL UA 1336, NEEDLE GUIDE FOR 8824, MODEL UA 1337 (K083667)	B-K Medical

The purpose of this 510(k) is to modify the device design to 1) allow the guide to attach to the OEM ultrasound transducer via a customized bracket or directly attach to the OEM ultrasound transducer housing, 2) expand the range of gauge inserts, and 3) increase the guide angle range.

C. Device Description

The ultrasound guidance system is used during diagnostic or therapeutic procedures to assist the clinician in placing an interventional device in a targeted anatomical location. The guidance system consists of a guide, gauge inserts, and may include a bracket. The guide attaches to the OEM ultrasound transducer via a VerzaLink™ locating feature either on the customized bracket (Figure 1) or on the OEM ultrasound transducer housing (Figure 2). The guide is secured to the locating feature using a locking mechanism.

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Figure 1 – VerzaLink™ Locating Feature on Bracket

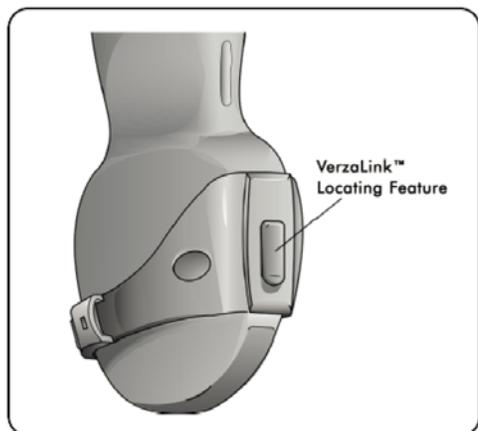
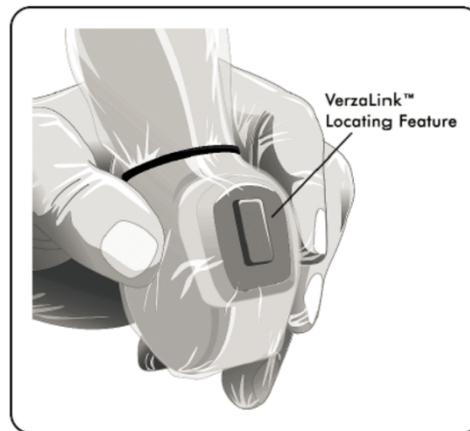


Figure 2 – VerzaLink™ Locating Feature on Transducer



The angle of the guide adjusts within a 37° range by moving the angle selector grip proximally or distally on the guide. The angle is secured into place at the desired position using a locking mechanism.

The guide receives the gauge inserts. The gauge inserts are provided on a gauge insert tree in sizes ranging from 12F to 25G. Rotation of a quick-release tab on the gauge insert enables the guide and OEM ultrasound transducer to be removed while leaving the interventional instrument in place.

The guide and gauge inserts are provided sterile, and are intended for single-use. The bracket is provided non-sterile and is reusable. The device is for use by a medical professional in a physician office, clinic, or hospital environment. The following models are included in this submission:

Part No.	Device Name	Contents
610-1500-24	Verza™ Guidance System	Verza™ guides for use with VerzaLink™ enabled transducers and brackets, and CIV-Flex™ covers
642-497	Verza™ Guidance System	Reusable, non-sterile bracket for use with GE C1-6-D transducers, Verza™ guides, and CIV-Flex™ covers

D. Indications for Use/Intended Use

The system provides guidance for precise instrument placement of common interventional devices by positioning the device relative to the ultrasound transducer and the resulting image during a diagnostic or therapeutic procedure. This guidance system is intended for use with pediatric and adult patients.



E. Comparison of Technological Characteristics

Both the proposed and predicate guidance systems provide a means for placement of common interventional devices by positioning the interventional device relative to the ultrasound transducer during a diagnostic or therapeutic procedure. Technological characteristics that differ between the proposed and predicate guidance systems include changes in design. Both the proposed and predicate systems consist of a guide and gauge inserts, and may include a bracket or clip. Both guidance systems offer a range of guidance angles, but on the predicate system the angle is created through channels in the gauge inserts whereas on the proposed system the angle is created through angular adjustment of the guide. The gauge inserts for both the predicate and proposed system are placed into the guide and the size is selected to accommodate the size of the interventional instrument. The gauge insert sizes for the predicate system range from 10G to 20G while the proposed system ranges from 12F to 25G. The proposed system may be mounted to the ultrasound transducer via a bracket whereas the predicate system may mount via a wire clip. Alternatively, both the proposed and predicate guidance systems are able to mount directly to the OEM ultrasound transducer. The predicate guidance system snaps onto grooves on the transducer whereas the proposed guidance system is attached to an external locating feature on the transducer and secured using a locking mechanism. Similar plastic and metal materials are used to manufacture the predicate and proposed devices.

F. Non-Clinical Testing

Non-clinical testing was completed to confirm that the proposed guidance system is as safe and effective as the predicate guidance system and that the differences in technological characteristics do not raise any new issues of safety or effectiveness. Testing relating to 1) attachment of the guide to the locating feature on the transducer bracket or on the OEM ultrasound transducer housing, 2) an expanded range of gauge inserts, and 3) an increased guide angle range met the acceptance criteria and confirmed that the new design features have not diminished the safety and effectiveness of the device. The proposed guidance system including a bracket was validated with the GE C1-6-D transducer. Biocompatibility testing was completed for patient-contacting materials according to ISO 10993-5, ISO 10993-10, ISO 10993-11, and ASTM F756. Clinical images were provided with the submission; these images were not necessary to establish substantial equivalence based on the modifications to the predicate device, but they provide further evidence in addition to the test performance data to show that the complete ultrasound guidance system works as intended.

G. Conclusion

This premarket submission for the Ultrasound General Purpose Guidance System has demonstrated substantial equivalence as defined and understood in the Federal Food, Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

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