K992152

AUG 17 1999

CIVCO MEDICAL INSTRUMENTS

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

(As required by 21 CFR 807.92)

Ultrasound Transducer Standoff

A. General Information

Submitter's Name:	CIVCO Medical Instruments Company, Inc.
Address:	102 First Street South, Kalona, IA 52247
Telephone No.:	phone (319) 656-4447 fax: (319) 656-4451
Contact Person:	J. William Jones, Manager - Regulatory Affairs

Establishment Registration Number: **1937223**
CIVCO Medical Instruments is registered as a medical device manufacturer.

Device Trade:	**Ultrasound Transducer Standoff**
Device Common:	Ultrasound Transducer Standoff
Device Classification Name:	Ultrasonic Diagnostic Transducer Accessories
Classification:	Class II under 21 CFR 892.1570
Classification Panel:	Radiology
Classification Procode:	90 ITX

Performance Standards: No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.

B. Device Description

The **Ultrasound Transducer Standoff** device provides a firm, conformal fit to the ultrasound transducer that elevates the transducer from the body surface for near-field imaging. The standoff device provides a fixed height to which the sound transmits through allowing the focal zone of the transducer to be repositioned on near field tissue. Standoff materials are **silicone or urethane elastomers**. The standoff device material's purpose is to provide a media to offset the transducer from the body surface to be scanned, thereby, shifting the focal zone of the transducer, while still providing a media through which the user can obtain an acceptable image visualization of near-field and superficial structures. Transmission of the sound through the standoff material should not introduce a large amount, if any, of distortion and artifacts, nor absorb a great deal of sound.

Standoff devices are custom designed to each, specific ultrasound transducer geometry and scanning depth needs. Product categories / models include:

General Purpose Transducer Standoff [integral self-bracketing type]

Biopsy Transducer Standoff [standoff inserts into needle guide bracket]

Bi-Plane Endocavity Transducer Standoff

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The standoff device is offered in three configurations:

1. one-piece, flexible conformal-fit to transducer design [Figures A & B]
2. two-piece design - a flexible standoff "insert" captured by a rigid plastic transducer bracket with or without needle guidance capability [Figure C]
3. one-piece, flexible conformal-fit endocavity design [Figure D].

Configurations of Ultrasound Transducer Standoffs

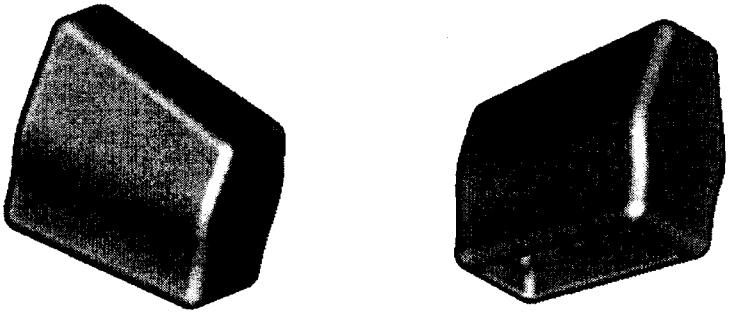

Figure A

Self-bracketing wedge configuration is solid silicone or urethane material, or may be solid material encapsulating an inner silicone gel material depending on design requirements and specifications.

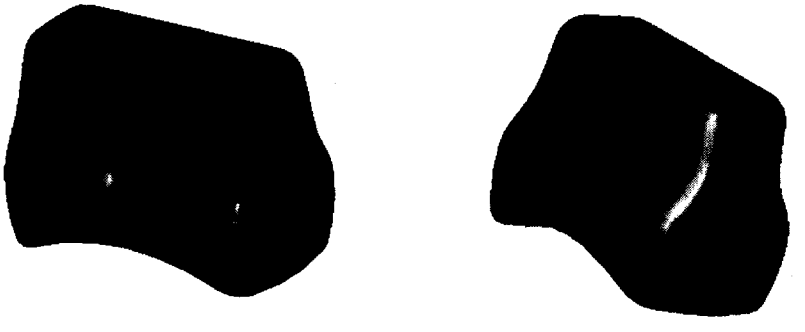

Figure B

Self-bracketing flat configuration is solid silicone or urethane material, or may be solid material encapsulating an inner silicone gel material depending on design requirements and specifications.

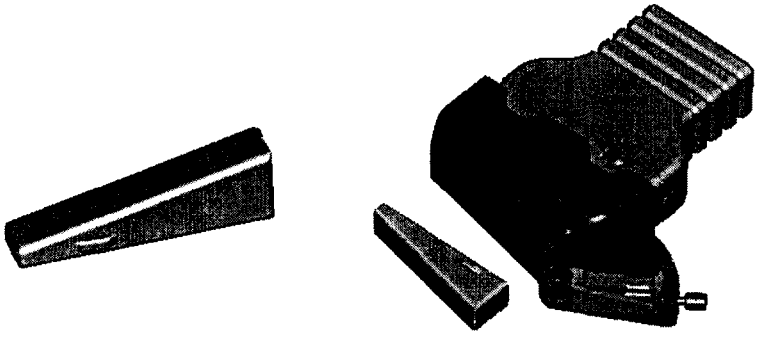

Figure C

Wedge configuration for inserting into biopsy bracket is solid silicone or urethane material, or may be solid material encapsulating an inner silicone gel material depending on design requirements and specifications. Standoff is captured inside the bracket. An advantage to this design is the reduced risk of puncturing the standoff during a needle biopsy procedure.

Figure D

Endocavity standoff is solid silicone material, or may be solid silicone material encapsulating an inner silicone gel material depending on design requirements and specifications.

Standoffs are installed against the face of the transducer with a small amount of gel at the interface to provide adequate ultrasonic coupling. Instructions for use include the recommendation for always using a transducer cover in endocavity and/or needle puncture procedures.

Standoff devices have limited reuse capability (# of reuses per instructions for use) if properly cleaned / disinfected. The level of disinfection or sterilization should be appropriate for the intended clinical use. Reprocessing of the standoff device is required between single patient uses and can be accomplished using the following validated methods - cleaning with enzymatic detergent & water; disinfection / sterilization by 2% glutaraldehyde based solution; sterilization of solid one-piece (silicone only) standoffs can be accomplished by steam autoclaving.

Standoff devices are packaged in a non-sterile "procedure kit" form. Standoff devices are furnished separately and in procedure kits supplied with transducer covers, and with or without coupling gel packet. Standoff devices are also combined with needle guide devices into custom kits that CIVCO builds for ultrasound OEMs and end users.

C. Intended Use / Indications for Use

The **Ultrasound Transducer Standoff** is placed over a diagnostic ultrasound transducer / probe / scanhead to control the distance (offset) between transducer and body surfaces for optimal focusing by shifting the transducer, effectively offsetting the focal zone, for improved visualization of near-field and superficial structures. The transducer standoff device can be used to perform scanning and needle guided procedures for body surface and endocavity diagnostic ultrasound. Standoff devices are furnished as a non-sterile; single use patient / procedure, with limited reuse capability (as designated in instructions for use) if properly cleaned / disinfected between patient uses.

The intended use and indications for use place **Ultrasound Transducer Standoffs** in device body contact categories as follows:

a) surface devices, intact skin / mucosal membranes / breached surfaces, limited contact duration (< 24 hours)

Note: The urethane material will be restricted to surface, skin contact only.

D. Predicate Device(s)

The **Ultrasound Transducer Standoff** device is identified as substantially equivalent to the following legally marketed device(s):

Predicate Device(s)	510(k) Reference	Manufacturer
Aquaflex® Ultrasound Gel Pad	K851895	Parker Laboratories
Proxon Sector-Scan Standoff*	K873159	Cone Instruments

**included in Cone Instruments Combison 310A ultrasound scanner 510(k).*

Standoff Kit EA 4015	addition to 510(k) file**	B&K Ultrasound Systems

*** July 1997 for 510(k)s K936024, K943315, K905198, K914945, K933056.*

E. Substantial Equivalence Summary

The **Ultrasound Transducer Standoff** is substantially equivalent in safety and effectiveness to the predicate device(s). The comparison table on the following page demonstrates this substantial equivalence.

Comparison of Device to Substantially Equivalent, Legally Marketed Device

Parameter	Ultrasound Transducer Standoff	Predicate Devices Ultrasound Standoffs / Gel Pad
Intended Use / Indications for Use	Same.	The **Ultrasound Transducer Standoff** is placed over a diagnostic ultrasound transducer / probe / scanhead to control the distance (offset) between transducer and body surfaces for optimal focusing by shifting the transducer, effectively offsetting the focal zone, for improved visualization of near-field and superficial structures. The standoff device is used to perform scanning of body surface and endocavity anatomy.
Design	Same. [self-bracketing, conformal type] ▪ Additional to CIVCO design is a two-piece standoff insert / bracket design for use with needle guide bracket devices.	▪ One-piece pad type. ▪ Self-bracketing conformal to transducer geometry configurations.
Material	▪ **Synthetic Elastomeric Polymers:** ▫ **Silicone rubber** [*same as B&K Ultrasound material*] ▫ **Silicone gel** ▫ **Urethane**	▪ Aqueous polymer gel [Parker Labs] ▪ Polyvinylchloride (PVC), *Sonogel® Proxon* [Cone Instruments] ▪ Silicone rubber [B&K Ultrasound]
Manufacturing	Same.	▪ Gel pad [Parker Labs] solidified gel by casting. ▪ Sector Scan Standoff [Cone Inst.] by injection molding (*mfg. by Sonogel ® for Kretztechnik / Cone*) ▪ EA4015 Standoff [B&K Ultrasound] by injection molding (*mfg. by CIVCO Medical for B&K*)
Quality Systems	Same.	▪ FDA/QSR cGMP 21CFR Part 820. ▪ ISO 9001 / EN46001 / ISO 13485.

Comparison of Device to Substantially Equivalent, Legally Marketed Device cont.

Parameter	Ultrasound Transducer Standoff	Predicate Devices Ultrasound Standoffs / Gel Pad
Sterility	Same. ▪ Devices are furnished non-sterile and intended for limited reuses. ▪ Reprocess by user: clean with enzymatic detergent / disinfect or sterilize by cold chemical solution / sterilize solid silicone configurations with steam autoclave. ▪ Reusables are validated for chemical compatibility and reprocessing method(s) per *Design, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers*, AAMI TIR No. 12-1994 and *Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance*, ODE.	▪ Reusables and single-use disposables [Parker Labs] are furnished non-sterile. ▪ Reusables can be reprocessed by the user: clean by detergent & water / disinfect by alcohol based spray.
Device Body Contact Category	Same.	▪ surface devices, intact skin / mucosal membranes / breached surfaces; limited contact duration (< 24 hours).
Safety	Biocompatibility tests for cytotoxicity, acute systemic toxicity, irritation, and sensitization have demonstrated the **silicone rubber, silicone gel, and urethane** materials / standoff devices are: ▪ non-toxic. ▪ non-irritating. ▪ non-sensitizing; and, thereby, safe for use as a surface device contacting intact skin / mucosal membranes / breached surfaces. Testing is in accordance with - ISO 10993-Part 1 Biological Evaluation of Medical Devices, FDA Blue Book Memorandum #G95-1, and FDA-Good Laboratory Practices (GLP).	The historical sale and use of these devices have place them in the generally regarded as safe category for their intended use. CIVCO has performed biocompatibility tests [*cytotoxicity, acute systemic toxicity, irritation, and sensitization*] that has demonstrated that the Parker gel pad and B&K silicone devices / materials are: ▪ non-toxic. ▪ non-irritating. ▪ non-sensitizing. Note: The Proxon Standoff [Cone] PVC material is not suitable for use on "infected, inflamed or broken tissue" per the instructions for use.

Comparison of Device to Substantially Equivalent, Legally Marketed Device cont.

Parameter	Ultrasound Transducer Standoff	Predicate Devices Ultrasound Standoffs / Gel Pad
Effectiveness	Evaluation testing of the **Ultrasound Transducer Standoff** has shown that the silicone and urethane materials are adequate for the intended use: ▪ Mechanical properties of the material allows for rigid conformal fit to the transducer, while the elastomeric characteristics of the material is flexible for conformance to surfaces being scanned. ▪ Material has been demonstrated capable, using a quality assurance phantom, of shifting the transducer to improve the visualization of near-field and superficial structures.	Historical marketing / sales and successful user experiences have demonstrated the effectiveness of these predicate standoff devices.

F. Conclusions

This premarket submission for the **Ultrasound Transducer Standoff** 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 1999

J. William Jones
Regulatory Affairs Manager
CIVCO Medical Instruments Co., Inc.
102 First Street South
Kalona, IA 52247

Re: K992152
Ultrasound Transducer Standoff
Dated: June 24, 1999
Received: June 25, 1999
Regulatory Class: II
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K992152

Device Name: Ultrasound Transducer Standoff

Indications For Use:

The **Ultrasound Transducer Standoff** is placed over a diagnostic ultrasound transducer / probe / scanhead to control the distance (offset) between transducer and body surfaces for optimal focusing by shifting the transducer, effectively offsetting the focal zone, for improved visualization of near-field and superficial structures. The transducer standoff device can be used to perform scanning and needle guided procedures for body surface and endocavity diagnostic ultrasound. Standoff devices are furnished as a non-sterile; single use patient / procedure, with limited reuse capability (as designated in instructions for use) if properly cleaned / disinfected between patient uses.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992152

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)