



K970514  
June 20, 1997

**510(k) Summary - Disposable Endocavity Ultrasound Needle / Biopsy Guide**

Date Summary Prepared: 31 January 1997

*This summary of the safety and effectiveness information upon which the substantial equivalence determination is based is being submitted in accordance with the requirements of SMDA 1990.*

**Submitter's Name:** CIVCO Medical Instruments Company, Inc.  
**Address:** 102 First Street South, Kalona, IA 52247  
**Telephone No.:** (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 / Proprietary Name:** Disposable Endocavity Ultrasound Needle / Biopsy Guide  
**Device Common / Usual Name:** Ultrasound Transducer Needle / Instrument Guide  
**Device Classification Name:** Ultrasonic Diagnostic Transducer Accessories

**Classification:** Class II under 21 CFR 892.1570  
**Classification Panel:** 90 Radiology  
**Classification Procode:** ITX

**Description of Predicate Device(s):** The CIVCO Disposable Endocavity Ultrasound Needle / Biopsy Guide is equivalent to CIVCO's currently, legally marketed Transrectal Needle/Biopsy Guide, 510(k) reference number K875128/A, and Transvaginal Needle/Biopsy Guide, 510(k) reference number K875240/A.

**Description of Subject Device Submitted for Premarket Notification:** - The subject device provides a fixed path by which to allow needle / instrument guidance in relationship to a specific ultrasound transducer geometry. Various sizes and shapes of endocavity needle guides are engineered and manufactured by CIVCO - each is designed to fit to a specific OEM ultrasound transducer or family of transducers.

**ORIGINALS ARE CODED RED**

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**510(k) Summary con't. - Disposable Endocavity Ultrasound Needle / Biopsy Guide****Description of Subject Device Submitted for Premarket Notification con't.**

The endocavity guide design integrates the mounting bracket and cannula into a single, disposable component that attaches externally, over the transducer with a clip-on action. The removal process is accomplished by pulling the needle guide off the transducer in a reverse method from the application.

Typical guide designs are illustrated below.



Encased Cannula Styles



Open Cannula Styles

Design variables address the mounting features / dimensional characteristics / presentation angle necessary to accommodate differences in transducer geometries, and the cannula size (gauge) as required by the needle / instrument to be guided. Otherwise, needle guide configurations are essentially the same in appearance and function. All guides are designed for conformal fit with locator features for secure alignment to the transducer. Exterior shapes of the needle guide are contoured for patient comfort.

The device is furnished sterile; and the entire guide is single use patient / procedure, disposable. The single use, disposable feature helps to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer.

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**ORIGINALS ARE CODED RED**

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**510(k) Summary con't. - Disposable Endocavity Ultrasound Needle / Biopsy Guide**

Product categories / models include:

Disposable Endocavity Needle Guide (sterile)

Disposable Transrectal Needle Guide (sterile)

Disposable Transvaginal Needle Guide (sterile)

Endocavity needle guides are individually packaged in sterile "procedure kit" form for single patient / procedure, disposable use. "Procedure kits" are also available with Poly and Latex transducer covers combined with disposable needle guide devices that CIVCO custom kits for ultrasound OEMs.

**Intended Uses:** This device provides a mechanical means for performing needle / instrument guided procedures with the use of the diagnostic ultrasound endocavity transducer. Needle guide is attached over endocavity transducer / probe / scanhead instruments. This device provides a fixed path for the needle or instrument that when coupled by the ultrasound system software corresponds to on-screen imaging guidelines for visualizing guided instrument placement procedures. CIVCO Endocavity Ultrasound Needle / Biopsy Guides are furnished sterile; single use patient / procedure, disposable. The single use, disposable feature helps to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer.

**Indications for Use:** Diagnostic ultrasound needle / instrument guided procedures - transvaginal and transrectal: tissue biopsy, fluid aspiration, catheter placement, and treatment.

The intended use and indications for use place the CIVCO Disposable Endocavity Ultrasound Needle / Biopsy Guides in device body contact categories as follows:

- a) surface devices, intact skin / mucosal membranes / breached surfaces, limited contact duration (< 24 hours)
- b) external communicating devices, blood path indirect / tissue communicating, limited contact duration (< 24 hours)

**Comparison of Device to Substantially Equivalent, Legally Marketed Device(s):**

**Intended Use:** both subject and predicate devices provide a mechanical means for performing transrectal and/or transvaginal needle / instrument guided procedures with the use of the diagnostic ultrasound endocavity transducer. This device provides a fixed path for the needle or instrument that when coupled by the ultrasound system software corresponds to on-screen imaging guidelines for visualizing guided instrument placement procedures.

Predicate devices utilize a reusable guide bracket (after cleaning / sterilization by user); and a sterile, single use, disposable cannula insert.

The subject device is furnished sterile; and the entire guide is single use patient / procedure, disposable. The single use, disposable feature helps to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer.

**Design:** Predicate devices are comprised of two components - 1) a reusable guide mount or bracket that securely attaches (wrap-around clamp or slide-on) external to the transducer at a fixed position, and 2) a disposable stainless steel cannula or plastic tube that snap fits into a slot on the reusable component.

The subject device integrates the mounting bracket and cannula into a single, disposable component that attaches externally, over the transducer with a clip-on action. The removal process is accomplished by pulling the needle guide off the transducer in a reverse method from the application.

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ORIGINALS ARE CODED RED

**510(k) Summary con't. - Disposable Endocavity Ultrasound Needle / Biopsy Guide****Comparison of Device to Substantially Equivalent, Legally Marketed Device(s) con't:**

**Material:** Predicate devices : thermoplastics (polycarbonate, nylon, acetal) and stainless steel (T304 Hypodermic Grade tubing).

Subject devices: thermoplastics ( ABS, polycarbonate) and stainless steel (T304 Hypodermic Grade tubing). These materials have been effectively used in CIVCO ultrasound endocavity needle guide applications for the past seven (7) years.

**Manufacture:** Predicate devices: machined fabrications from thermoplastic extruded / molded standard shapes and stainless steel tubing.

Subject devices: fabricated from 1) injection molded thermoplastic components, bonded to stainless steel cannula with medical grade adhesive; and 2) injection insert-molded thermoplastic with integral stainless steel cannula.

Subject devices are manufactured in large lots for single use - disposable applications, and are furnished sterile. Procedure kit packaging (in class 10,000 cleanroom) and EtO sterilization are same as for disposables used with the predicate devices.

**Safety:** materials and manufacturing processing (including EtO sterilization) affects to the healthcare worker and patient via intended use / indications for use contact of this device have been biologically evaluated using biocompatibility tests for cytotoxicity, acute systemic toxicity, irritation, sensitization, hemolysis, and material mediated pyrogen. 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). CIVCO Disposable Ultrasound Endocavity Biopsy / Needle Guide products / materials have been evaluated for safe use under device categories of limited contact duration and body contact for surface devices (skin / mucosal membranes / breached surfaces) and body contact for external communicating devices (blood path indirect / tissue communicating). Biocompatibility testing was conducted using sterilized (where applicable), finished devices. Testing has demonstrated subject materials / devices to be **non-toxic, non-sensitizing, non-irritating, non-hemolytic, and non-pyrogenic.**

**Effectiveness:** Both the subject and predicate devices guides are designed for secure and aligned fit to the transducer, while not altering the transducer design integrity or function. Positive registration features of the design assures accurate needle / instrument path and placement in relation to the transducer. Attachment and removal of the subject device is simplified vs. the predicate device. Exterior shapes of the needle guides are contoured for patient comfort with no sharp edges. The integrated one-piece design of the subject device improves effectiveness since the reprocessing (clean, disinfect, sterilize) issues for a reusable device such as the predicate device is eliminated by the sterile, single use, disposable feature. Injection molding manufacturing process assures part-to-part accuracy for repeatable product performance.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 20 1997

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

Re: K970514  
Disposable Endocavity Ultrasound  
Needle/Biopsy Guide  
Dated: June 2, 1997  
Received: June 3, 1997  
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 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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.  
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**

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510(k) Number (if known): K970514

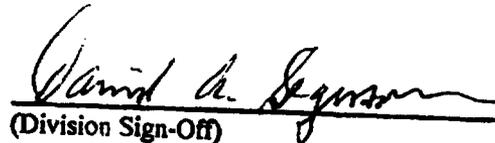
Device Name: Disposable Endocavity Ultrasound Needle / Biopsy Guide

Indications For Use:

Diagnostic ultrasound needle / instrument guided procedures - transvaginal and transrectal: tissue biopsy, fluid aspiration, catheter placement, and treatment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K970514

Prescription Use              
(Per 21 CFR 801.109)

OR

Over-The-Counter Use           

(Optional Format 1-2-96)