K970573

JUN 20 1997

CIVCO MEDICAL INSTRUMENTS

Solutions for Ultrasound

510 (k) SUMMARY — CIVCO Poly Ultrasound Transducer Cover

Date Summary Prepared: 30 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.
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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:	CIVCO Poly Ultrasound Transducer Cover
Device Common / Usual Name:	Ultrasound Transducer Cover / Sheath / Drape
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 Poly Ultrasound Transducer Cover is equivalent to CIVCO's currently, legally marketed Scan Drape, 510(k) reference number K844472.

ORIGINALS ARE CODED RED

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510 (k) SUMMARY con't. CIVCO Poly Ultrasound Transducer Cover

Description of Subject Device Submitted for Premarket Notification: CIVCO Poly Ultrasound Transducer Cover - this device provides an efficient, conformal covering to fit various & specific ultrasound transducer geometries. Devices are manufactured as a one-piece design that provides a covering that helps prevent the transmission of pathogens from one patient to another. Materials are polyurethane (CIV-Flex™) and polyethylene extruded thermoplastic film.

Ultrasound imaging is not impaired by use of the cover as it is intended. Adequate coupling between the cover and the transducer is required - the sterile or non-sterile Poly Ultrasound Transducer Cover is utilized by applying sterile transmission, coupling, or lubricating gel onto the transducer face or into closed end of cover, inserting ultrasound transducer into closed end of cover and unrolling cover over length of the transducer as desired, and securing open end of cover with bands as necessary. The removal process is accomplished by pulling the cover off the transducer in a reverse method from the application.

Various sizes and shapes of covers are offered in order to customize the fit to specific transducer geometries. Product categories / models include:

General Purpose CIV-Flex™ (polyurethane) Transducer Covers (sterile and non-sterile)
General Purpose Polyethylene Transducer Covers (sterile and non-sterile)
Accordion-folded Polyethylene Transducer Covers (sterile)
Intraoperative Polyethylene Transducer Covers (sterile)
Endocavity CIV-Flex™ (polyurethane) Transducer Covers (sterile and non-sterile)
Surgi™ Intraoperative (polyethylene) Transducer Covers (sterile)
Intraoperative (polyethylene) Cord and System Drapes (sterile)

Covers are packaged in both sterile and non-sterile "procedure kit" form for single patient / procedure, disposable use. Cover kits are supplied with fasteners, and with or without coupling gel packet. Poly transducer covers are also combined with disposable needle guide devices that CIVCO custom kits for ultrasound OEMs.

Intended Use / Indications for Use: Protective cover or sheath placed over diagnostic ultrasound transducer / probe / scanhead instruments. The cover allows use of the transducer in scanning and needle guided procedures for body surface, endocavity, and intra-operative diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids, and material to the patient and healthcare worker during reuse of the transducer (both sterile and non-sterile covers). The cover also provides a means for maintenance of a sterile field (sterile covers only). CIVCO Poly Ultrasound Transducer Covers are furnished sterile & non-sterile; single use patient / procedure, disposable.

The intended use and indications for use place CIVCO Poly Ultrasound Transducer Covers 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)

510 (k) SUMMARY con't. CIVCO Poly Ultrasound Transducer Cover

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

Intended Use: both provide a thin, conformal protective cover system for ultrasound transducer usage in body surface, endocavity, and intra-operative patient environments; both help to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer, and help maintain the sterile field where applicable; both are disposable devices - for single patient / procedure use.

Design: both are one-piece, open on one end, closed on other end with various dimensional configurations necessary to accommodate differences in ultrasound transducer geometries. Covers are externally applied to ultrasound transducer.

Material: Cover materials are polyurethane (CIV-Flex™) and polyethylene extruded thermoplastic film; polyurethane and polyethylene materials have been effectively used in CIVCO ultrasound transducer covers applications for the past ten (10) years.

Manufacturing: manufacturing processes - impulse heat-seal cover fabrication, packaging (in class 10,000 cleanroom), and EtO sterilization (when applicable) are same as for predicate device.

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 Polyurethane and Polyethylene Ultrasound Transducer Cover 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: physical / mechanical properties of the finished device are the same as for that of the predicate device; material strength and elasticity is adequate to allow use without tearing or pinholing the cover - a) during application and removal of cover from transducer, b) during scanning under intended uses, and c) attaching / removing a disposable needle guide to the transducer bracket over the cover; CIVCO Polyurethane and Polyethylene Ultrasound Transducer Covers have been tested by an independent laboratory under protocol adapted from that used to evaluate the barrier properties / resistance of surgeons glove materials to penetration by bloodborne pathogens using viral penetration as a test system. This testing has demonstrated that the polyurethane and polyethylene transducer covers provide an effective barrier to the prevention of microbial migration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

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

Re: K970513
CIVCO Poly Ultrasound Transducer Cover
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 (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 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

Page 1 of 1

510(k) Number (if known): K970513

Device Name: CIVCO Poly Ultrasound Transducer Cover

Indications For Use:

Protective cover or sheath placed over diagnostic ultrasound transducer / probe / scanhead instruments. The cover allows use of the transducer in scanning and needle guided procedures for body surface, endocavity, and intra-operative diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer (both sterile and non-sterile covers). The cover also provides a means for maintenance of a sterile field (sterile covers only). CIVCO Poly Ultrasound Transducer Covers are furnished sterile & non-sterile; single use patient / procedure, disposable.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Lagerman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970513

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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