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510(k) SUMMARY OF SAFETY & EFFECTIVENESS

(As required by 21 CFR 807.92)

Synthetic Polyisoprene Ultrasound Transducer Cover

A. General Information

Submitter's Name: CIVCO Medical Instruments Co., Inc.
Address: 102 First Street South, Kalona, IA 52247
Telephone No.: phone (319) 656-4447 fax: (319) 656-4451
Contact Person: Theresa Leinen, Quality Systems Administrator

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

Device Trade: **Synthetic Polyisoprene Ultrasound Transducer Cover**
Device Common: Ultrasound Transducer Cover / Sheath / Drape
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 **Synthetic Polyisoprene Ultrasound Transducer Cover** provides a thin, conformal covering to fit various and specific ultrasound transducer geometries. The cover is manufactured as either a one-or two-piece design that provides a covering that helps prevent the transmission of pathogens as the ultrasound transducer is reused from one patient to another.

The cover material is **polyisoprene synthetic rubber** similar to that of non-latex medical examination / surgical gloves. Various sizes and shapes of covers are offered in order to customize the fit to specific transducer geometries. Product categories / models include:

General Purpose Synthetic Polyisoprene Transducer Covers (sterile and non-sterile)

Endocavity Synthetic Polyisoprene Transducer Covers (sterile and non-sterile)

Surgi-Tip™ Intraoperative* Synthetic Polyisoprene Transducer Covers (sterile)
*Polyethylene cord cover w/ Synthetic Polyisoprene tip

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. Transducer covers are also combined with disposable needle guide devices into custom kits that CIVCO builds for ultrasound OEMs and end users.

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C. Intended Use / Indications for Use

The **Synthetic Polyisoprene Ultrasound Transducer Cover** is a protective cover or sheath placed over an ultrasound transducer / probe / scanhead instruments. The cover is used with the transducer in scanning and needle guided procedures for body surface, endocavity, and intra-operative diagnostic, interventional, or therapeutic ultrasound. The cover also helps 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). **Synthetic Polyisoprene** is **latex-free** and therefore beneficial when treating a patient with known type I hypersensitivity, or for the healthcare worker who has become type I sensitized. Transducer covers are furnished sterile & non-sterile; single use patient / procedure, disposable.

The intended use and indications for use place **Synthetic Polyisoprene 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, tissue communicating, limited contact duration (< 24 hours)

D. Predicate Device

The Synthetic Polyisoprene Ultrasound Transducer Cover is identified as substantially equivalent to CIVCO's current, legally marketed NeoFlex™ Ultrasound Transducer Covers:

Predicate Device(s)	510(k) Reference	Manufacturer
NeoFlex™ Ultrasound Transducer Cover	K991236	CIVCO

E. Substantial Equivalence Summary

The **Synthetic Polyisoprene Ultrasound Transducer Cover** is substantially equivalent in safety and effectiveness to the CIVCO NeoFlex™ Ultrasound Transducer Cover. The comparison table on the following page demonstrates this substantial equivalence.

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Comparison of Device to Substantially Equivalent, Legally Marketed Device

Parameter	Synthetic Polyisoprene Ultrasound Transducer Cover	Predicate Device CIVCO NeoFlex™ Ultrasound Transducer Cover (K991236)
Intended Use / Indications for Use	Same.	Provides a thin, conformal protective cover system for ultrasound transducer usage in body surface, endocavity, and intra-operative patient environments; helps to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer, and helps to maintain the sterile field where applicable; disposable device - for single patient / procedure use.
Design	Same.	One-piece, closed end, rolled (condom style) or a two-piece , closed end cover, (synthetic rubber attached to polyethylene) with various dimensional configurations necessary to accommodate differences in ultrasound transducer geometries.
Material	▪ **Polyisoprene, synthetic rubber** ▪ Materials used in compounding meet the recommended safe levels as specified in the US Food and Drugs Administration CFR, Title 21, Section 177.2600 and 182.5991. ▪ USP Absorbable Dusting Powder. ▪ Synthetic rubber does not contain the natural protein allergen residuals present in latex.	▪ **Polychloroprene, synthetic rubber** ▪ Materials used in compounding meet the recommended safe levels as specified in the US Food and Drugs Administration CFR, Title 21, Section 177.2600 and 182.5991. ▪ USP Absorbable Dusting Powder. ▪ Synthetic rubber does not contain the natural protein allergen residuals present in latex.
Manufacturing	Same.	▪ dip-molding / rubber vulcanization. ▪ packaged in class 10,000 cleanroom per Federal Std 209e. ▪ packaging system per ANSI / AAMI / ISO 11607.

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

Parameter	Synthetic Polyisoprene Ultrasound Transducer Cover	Predicate Device CIVCO NeoFlex™ Ultrasound Transducer Cover (K991236)
Quality Systems	Same.	▪ FDA/QSR cGMP 21CFR Part 820. ▪ ISO 9001 / EN46001 / ISO 13485.
Sterility	Same.	▪ sterilization (when applicable) by 100% EtO method; ▪ validated ANSI / AAMI / ISO 11135. ▪ SAL 10^{-6}.
Device Body Contact Category	Same.	▪ surface devices, intact skin / mucosal membranes / breached surfaces; limited contact duration (< 24 hours) ▪ External communicating devices, tissue communicating; limited contact duration (< 24 hours)
Safety	Biocompatibility tests for cytotoxicity, acute systemic toxicity, irritation, sensitization, hemolysis, material mediated pyrogen, and ethylene oxide sterilization residuals have demonstrated the **Synthetic Polyisoprene** material / cover device is: ▪ non-toxic. ▪ non-sensitizing. ▪ non-irritating. ▪ non-hemolytic. ▪ non-pyrogenic. 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).	Biocompatibility tests for acute systemic toxicity, irritation, sensitization, hemolysis, material mediated pyrogen, and ethylene oxide sterilization residuals have demonstrated the NeoFlex™ material / cover device is: ▪ non-toxic. ▪ non-sensitizing. ▪ non-irritating. ▪ non-hemolytic. ▪ non-pyrogenic. 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).

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

Parameter	Synthetic Polyisoprene Ultrasound Transducer Cover	Predicate Device CIVCO NeoFlex™ Ultrasound Transducer Cover (K991236)
Effectiveness	Testing for **Synthetic Polyisoprene covers** has shown that the material is adequate for the intended use: ▪ Strength and elastic characteristics are effectively similar to that of NeoFlex™ and allows 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. ▪ Nominal thickness of .010". ▪ Ultrasound imaging is not impaired. ▪ **Synthetic Polyisoprene** transducer cover provides an effective barrier to the prevention of microbial migration – tested under protocol adapted from that used to evaluate the barrier properties / resistance of surgical gloves and endoscope sheaths to penetration by bloodborne pathogens using viral penetration as a test system. ▪ **Synthetic Polyisoprene** material is used for medical examination / surgical gloves.	Experience and testing has shown that polychloroprene (neoprene) covers: ▪ Neoprene has sufficient strength and elasticity for the intended application. ▪ Nominal thickness is .010". ▪ Does not impair ultrasound imaging. ▪ Are an effective barrier to the prevention of microbial migration.

F. Conclusions

This premarket submission for the **Synthetic Polyisoprene Ultrasound Transducer Cover** 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

DEC 2 8 2001

Ms. Theresa Leinen
Quality Systems Administrator
CIVCO Medical Instruments Co., Inc.
102 First Street South
KALONA IA 52247

Re: K013721
Trade/Device Name: Synthetic Polyisoprene Ultrasound Transducer Cover
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: 90 ITX
Dated: November 2, 2001
Received: November 9, 2001

Dear Ms. Leinen:

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.

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); 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.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013721

Device Name: Synthetic Polyisoprene Ultrasound Transducer Cover

Indications For Use:

Protective cover or sheath is placed over an 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 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 Synthetic Polyisoprene Ultrasound Transducer Covers are furnished sterile and 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013721

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