JUN 2 1999

K991236 (5 pages)

CIVCO MEDICAL INSTRUMENTS

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

(As required by 21 CFR 807.92)

NeoFlex™ Ultrasound Transducer Cover

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:	**NeoFlex™ 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 **NeoFlex™ Ultrasound Transducer Cover** device provides a thin, conformal covering to fit various & specific ultrasound transducer geometries. Device is manufactured as a one-piece design that provides a covering that helps prevent the transmission of pathogens as the ultrasound transducer is reused from one patient to another.

Cover material is **polychloroprene (neoprene) synthetic rubber** similar to that of non-latex medical examination / surgical gloves. Type I natural latex allergy does not occur in response to polychloroprene synthetic rubber since the synthetic rubber does not contain the natural protein allergen residuals present in latex.

CIVCO North America
02 First Street South
Kalona, IA 52247-9589 USA
Phone: 319.656.4447
Fax: 319.656.4451
www.civcomedical.com

CIVCO Europe
Avenue Louise 65, box 11
1050 Brussels Belgium
Phone: +32(02)535.7881
Fax: +32(02)535.7700
www.civcomedical.com

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

General Purpose NeoFlex™ Transducer Covers (sterile and non-sterile)

Endocavity NeoFlex™ Transducer Covers (sterile and non-sterile)

Surgi-Tip™ Intraoperative* Transducer Covers (sterile)
*polyethylene cord cover w/ NeoFlex™ 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.

C. Intended Use / Indications for Use

The **NeoFlex™ Ultrasound Transducer Cover** is a 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). **NeoFlex™** 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 **NeoFlex™ 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 NeoFlex™ Ultrasound Transducer Cover device is identified as substantially equivalent to CIVCO Medical's currently, legally marketed Latex Ultrasound Transducer Covers:

Predicate Device(s)	**510(k) Reference**	**Manufacturer**
Latex Ultrasound Transducer Cover	K970515	CIVCO Medical

E. Substantial Equivalence Summary

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

Comparison of Device to Substantially Equivalent, Legally Marketed Device

Parameter	NeoFlex™ Ultrasound Transducer Cover	Predicate Device CIVCO Latex Ultrasound Transducer Cover (K970515)
Intended Use / Indications for Use	Same. Additionally, **NeoFlex™** is **non-latex** and therefore beneficial when treating a patient with known type I hypersensitivity, or for the healthcare worker who has become type I sensitized.	Provides a thin, conformal protective cover system for diagnostic 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) with various dimensional configurations necessary to accommodate differences in ultrasound transducer geometries.
Material	▪ **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.**	▪ **Latex, natural 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.
Manufacturing	Same.	▪ dip-molding / rubber vulcanization. ▪ packaged in class 10,000 cleanroom per Federal Std 209e. ▪ packaging system per ANSI / AAMI / ISO 11607.

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

Parameter	NeoFlex™ Ultrasound Transducer Cover	Predicate Device CIVCO Latex Ultrasound Transducer Cover (K970515)
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 acute systemic toxicity, irritation, sensitization, hemolysis, material mediated pyrogen, and ethylene oxide sterilization residuals have demonstrated the **NeoFlex™ polychloroprene** 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). **Type I natural latex allergy does not occur in response to polychloroprene synthetic rubber.**	Biocompatibility tests for acute systemic toxicity, irritation, sensitization, hemolysis, material mediated pyrogen, and ethylene oxide sterilization residuals have demonstrated the latex 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).

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

Parameter	NeoFlex™ Ultrasound Transducer Cover	Predicate Device CIVCO Latex Ultrasound Transducer Cover (K970515)
Effectiveness	Testing for **NeoFlex™ polychloroprene covers** has shown that the material is adequate for the intended use: ▪ strength and elastic characteristics are effectively similar to that of latex 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. ▪ same nominal thickness of .0065". ▪ ultrasound imaging is not impaired. ▪ **NeoFlex™ polychloroprene** 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. ▪ **polychloroprene (neoprene)** material is used for medical examination / surgical gloves.	Experience and testing has shown that latex natural rubber covers: ▪ latex has sufficient strength and elasticity for the intended application. ▪ nominal thickness is .0065". ▪ do not impair ultrasound imaging. ▪ are an effective barrier to the prevention of microbial migration.

F. Conclusions

This premarket submission for the **NeoFlex™ 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

JUN 2 1999

J. William Jones
Regulatory Affairs Manager
Civco Medical Instruments Company, Inc.
102 Fist Street South
Kalona, Iowa 55247

RE: K991236
NeoFlex Ultrasound Transducer Cover
Dated: April 8, 1999
Received: April 12, 1999
Regulatory Class: II
21 CFR 892.892.1570/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): K991236

Device Name: NeoFlex™ 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 NeoFlex™ 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 G. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991236

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