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JUN 11 2013

Section 5 – 510(k) Summary

A. Submitter Information

Submitter Name & Address: CIVCO Medical Instruments Co., Inc. d/b/a CIVCO Medical Solutions
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Kalona, Iowa 52247

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Date Summary Prepared: September 10, 2012

Trade Name: Non-Pyrogenic CIV-Flex™
Non-Pyrogenic NeoGuard™ SurgiTip™
Non-Pyrogenic NeoGuard™
Common Name: Non-Pyrogenic Ultrasound Transducer Cover
Classification Name: Transducer, Ultrasonic, Diagnostic
Classification Number: Class II under 21 CFR 892.1570
Review Panel: Radiology
Product Code: ITX

B. Predicate Device

The proposed Non-Pyrogenic Ultrasound Transducer Cover is substantially equivalent to the following predicate devices:

Predicate Devices	Mfg.
K970513: General Purpose Transducer Cover Materials: Polyurethane and Polyethylene	CIVCO Medical Instruments Co., Inc.
K013721: Synthetic Polyisoprene Ultrasound Transducer Cover Materials: Synthetic Polyisoprene	CIVCO Medical Instruments Co., Inc.

The proposed device and the predicate devices are comprised of equivalent materials and have the same design. The purpose of this 510(k) is to expand the indications for use of these predicate devices to include use in the central nervous system and add the claim of non-pyrogenic. These additional indications of use are supported by test data and this testing has demonstrated that the device is safe and effective for these additional intended uses.

C. Device Description

The Non-Pyrogenic Ultrasound Transducer Cover provides a thin, conformal covering to fit a variety of ultrasound transducer geometries. The cover is made of polyurethane,

polyethylene, and/or synthetic polyisoprene materials. The cover is manufactured as either a one-or two-piece design that helps prevent the transmission of pathogens as the ultrasound transducer is reused from one patient to another. The Non-Pyrogenic Ultrasound Transducer Cover is provided sterile and is single patient / procedure and disposable.

Ultrasound imaging is not impaired by use of the cover as it is intended. As adequate coupling between the cover and the transducer is required, the Non-Pyrogenic Ultrasound Transducer Cover is utilized by applying sterile saline or other non-pyrogenic coupling media onto the transducer face or into the closed end of cover, inserting the ultrasound transducer into the closed end of cover, and unrolling the cover over the length of the transducer as desired. The open end is secured with elastic bands and nylon clips as necessary. The removal process is accomplished by pulling the cover off the transducer in a reverse method from the application.

The following models of Non-Pyrogenic Ultrasound Transducer Covers are included in this submission:

Non-Pyrogenic Ultrasound Transducer Cover		**Accessories**
Product Name	**Material(s)**	
Non-Pyrogenic CIV-Flex™ (7.6 tapered to 4.1 x 147cm)	Polyurethane	Kraton elastic bands
Non-Pyrogenic CIV-Flex™ (10.2 x 147cm)	Polyurethane	Kraton elastic bands
Non-Pyrogenic NeoGuard™ SurgiTip™ (15.2 x 244cm with 3cm tip)	Synthetic Polyisoprene, Polyethylene	Kraton elastic bands, nylon clips
Non-Pyrogenic NeoGuard™	Synthetic Polyisoprene	Kraton elastic bands

D. Indications for Use/Intended 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, central nervous system, 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. The cover also provides a means for maintenance of a sterile field. The cover is single use patient / procedure, non-pyrogenic, and disposable.

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E. Technological Characteristics

No technological characteristics have changed between the proposed device and predicate devices. Both the predicates and the proposed device are comprised of equivalent materials (polyurethane, polyethylene, and/or synthetic polyisoprene). The predicate devices and the proposed device are identical in design.

F. Non-Clinical Testing

In order to support the expanded indications for use to include a non-pyrogenic claim and use in the central nervous system, non-clinical endotoxin testing per USP<85> Bacterial Endotoxins Test and implant testing per ISO 10993-06 Tests for Local Effects After Implantation was completed on the proposed device. The endotoxin testing demonstrated that pyrogen levels are acceptable in accordance with USP<161> Transfusion and Infusion Assemblies and Similar Medical Devices. The implant testing demonstrated that the device materials are non-reactive when implanted in muscle for one week.

Sterility, packaging, shelf life, biocompatibility, and performance testing completed on the predicate devices remains applicable for the proposed device and this testing is summarized in the submission.

G. Conclusion

This premarket submission for the Non-Pyrogenic 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. Based on comparison against predicate devices, endotoxin testing, and implant testing, the Non-Pyrogenic Ultrasound Transducer Cover is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 11, 2013

CIVCO Medical Instruments Co., Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K131528
Trade/Device Name: Non-Pyrogenic Ultrasound Transducer Covers
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer (accessory)
Regulatory Class: II
Product Code: ITX
Dated: May 24, 2013
Received: May 28, 2013

Dear Mr. Job:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

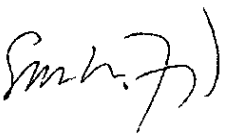
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131528

Device Name: Non-Pyrogenic 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, central nervous system, 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. The cover also provides a means for maintenance of a sterile field. The cover is single use patient / procedure, non-pyrogenic, and disposable.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K131528