K090773

SEP 18 2009

Medical Solutions
contour fabricators, inc.

510(k) Summary

510(k) Owner	Contour Fabricators, Inc. ("CFI")
Address	14241 Fenton Road, Fenton, MI 48430
Voice Number	(810) 750-5300
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Name of Contact Person	John W. Schaefer, Regulatory Manager

Establishment Registration Number 1825560

Contour Fabricators, Inc. is FDA registered as a medical device manufacturer.

Device Trade or Proprietary Name	CFI Ultrasound Probe Drape
Device Common or Usual Name	Ultrasound Probe Drape
Device Classification Name	System, Imaging, Pulsed Echo, Ultrasonic
Classification	Class II under 21 CFR 892.1560
Classification Panel	90 Radiology
Classification Product Code	IYO

Description of Devices Submitted for Premarket Notification:

Contour Fabricators, Inc. Ultrasound Probe Drapes provide an efficient flexible covering to fit various specific ultrasound probes. These ultrasound probe drapes are constructed primarily of polyurethane film, a customary ultrasound probe drape material.

Some drape designs additionally utilize an inner layer of polyethylene film to provide an extended cable cover. This extended cable cover has no patient contact and, at most, incidental user contact.

6 REVISED PAGES FOR SECTION "510(K) SUMMARY", TO BE SUBSTITUTED FOR ALL 6 EXISTING PAGES OF ORIGINAL SUBMISSION.

Most product versions include a pre-sterilized foil packet of ultrasound coupling gel and two sterile synthetic elastomer (non-latex) bands that are customarily used to control extra "bulk" of drape material in the vicinity of the application procedure.

Each Ultrasound Probe Drape is roll- or telescope-folded during its manufacturing to facilitate user application to the ultrasound probe. Each folded Ultrasound Probe Drape then is wrapped with a suitable piece of "CSR-wrap" (medical paper customarily used for this purpose). The wrapped, folded Ultrasound Probe Drape is then placed, along with the pre-sterilized foil packet of ultrasound coupling gel and the synthetic elastomer bands if provided, into a medical device pouch for terminal sterilization and distribution.

When the Ultrasound Probe Drape is used as intended, ultrasound imaging is not impaired. Adequate coupling between the Drape and the probe normally is accomplished by applying an appropriate amount of ultrasound coupling gel to the ultrasound probe before application of the Drape. Once the Drape is fully applied, any excess Drape material covering the probe cable is gathered by means of elastic bands for neatness and convenience and to hold the Drape in place. The removal process for the Ultrasound Probe Drape is accomplished by removing the elastic bands, pulling off the Drape, disposing of those materials, and appropriately cleaning any remaining gel from the ultrasound probe, in a reverse method from the application.

Evidence of compliance with ANSI/AAMI PB70, a Recognized Consensus Standard for barrier performance of Product Code KKX Surgical Drapes, and of independent-certified-laboratory determination of biocompatibility per Recognized Consensus Standard ISO 10993, is provided to demonstrate further equivalency to the predicate devices.

Description of Predicate Devices

The bundled Contour Fabricators, Inc. Ultrasound Probe Drape designs are based on, and are equivalent in dimensions, technology, materials, and intended use to selected ultrasound probe drapes that are manufactured by Civco Medical Instruments Company, Inc. and legally marketed per premarket notification K970513. A listing of specific equivalencies is provided in the Device Description section. Contour Fabricators, Inc. does not make equivalent models to all

models made by Civco, including Civco models made for certain applications that involve contact with broken skin, mucous membranes, and external blood paths. Therefore the scope of this premarket notification is less broad than that of the Civco 510(k) cited as the Predicate.

Intended Use / Indications for Use:

These ultrasound probe drape devices are intended for use by or as directed by a licensed medical practitioner during a medical ultrasound imaging procedure involving limited-duration unbroken-skin patient contact, to provide for maintenance of a sterile field (sterile covers only), to help protect the patient and healthcare worker from transfer of contaminants and biological risk agents (sterile and non-sterile covers), and to protect the ultrasound probe from contamination that could adversely affect its functionality or create downtime and require cleaning procedures (sterile and non-sterile covers). These single patient/procedure, disposable devices are furnished sterile and non-sterile, in most cases as an element of a kit-product that also includes a foil packet of ultrasound coupling gel, which always is pre-sterilized.

Comparison of Submitted Devices to Substantially Equivalent, Legally Marketed Devices

Intended Use:	Both device groups provide a thin, conformal protective cover / drape system for ultrasound transducer / probe usage in body-surface patient environments. Both help to provide for maintenance of a sterile field (sterile covers only), to help protect the patient and healthcare worker from transfer of contaminants and biological risk agents (sterile and non-sterile covers), and to protect the ultrasound probe from contamination that could adversely affect its functionality or create downtime and require cleaning procedures (sterile and non-sterile covers). Both are single patient/procedure, disposable devices, furnished sterile or non-sterile, in most cases as an element of a kit-product that also includes a foil packet of ultrasound coupling gel, which always is pre-sterilized.
Design:	Both device groups are configured as tubular bags or loose "socks", open on

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	one end and closed on the other end, with various dimensional configurations as necessary to accommodate differences in ultrasound transducer / probe geometries. Both are designed to be applied over the transducer / probe with the open end of the ultrasound probe drape extending along the connecting cable, and the closed end of the drape arranged against the working face of the transducer / probe.
Materials:	Both device groups are constructed primarily of polyurethane film, a customary ultrasound probe drape material. Polyurethane film has been effectively and safely used in ultrasound probe drapes for approximately twenty years. Some designs of both device groups additionally utilize polyethylene film, a customary material in medical-device drapes and covers, other medical disposables, pharmaceutical packaging and food containers and packaging. Polyethylene film has been effectively and safely used in medical-device, pharmaceutical and food applications for approximately thirty-five years. Most product versions include a pre-sterilized foil packet of ultrasound coupling gel and two sterile synthetic elastomer (non-latex) bands that are customarily used to control extra "bulk" of drape material in the vicinity of the application procedure. These devices normally are colorless-transparent, which is the natural (unpigmented) color of the polyurethane film and (if present) the polyethylene film. Ancillary components such as elastic bands (which normally do not have patient contact) may have other colors.
Manufacturing:	CFI's device group is made using validated heat-seal fabrication processes, with specification-compliance-controlling operations conducted in certified, validated ISO 14644-1:1999(E) Class 8 cleanrooms. Sterile barrier packaging (when applicable) is validated per ISO 11607. EtO sterilization (when applicable) is conducted by an appropriately certified, audited sterilization

	subcontractor utilizing processes validated per ISO 11135. All operations are subject to the CFI quality management system. The predicate device group is made using "impulse heat-seal cover fabrication, packaging (in class 10,000 cleanroom), and EtO sterilization (when applicable)".
Safety:	Both device groups have been evaluated for potential adverse effects to the healthcare worker and patient by means of biological testing by an appropriately certified test laboratory. Representative post-sterilization samples from CFI's device group were tested per Cytotoxicity Evaluation (ISO 10993-5:1999) per Fluid Extract/L929 Mouse Fibroblast; Primary Skin Irritation (ANSI/AAMI/ISO 10993-10:2002); Dermal Sensitization Maximization (ISO 10993-10:2002 (0.9% NaCl Extract); and Dermal Sensitization Maximization (ISO 10993-10:2002 (Cottonseed Oil Extract), for safe use under conditions of limited contact (<24 hours) and surface contact with unbroken skin, as appropriate for clinical applications of the CFI devices. This testing was conducted in accordance with FDA Good Laboratory Practice. Test results indicated best achievable scores for cytotoxicity, irritation and sensitization per these standards, which exceeds the "Pass" requirements for such testing. The broader range of predicate devices, with device models that have different clinical applications including invasive applications as indicated in their broader Intended Use, were evaluated for safe use under "ISO 10993-Part 1 Biological Evaluation of Medical Devices, FDA Blue Book Memorandum #G95-1, and FDA-Good Laboratory Practices (GLP)". Their similar materials were found to be non-toxic, non-sensitizing, non-irritating, non-hemolytic and non-pyrogenic.
Effectiveness:	Both device groups have essentially equal physical and mechanical properties, including material strength and elasticity that is adequate to allow use without tearing or pinholing the Ultrasound Probe Drape during the drape's

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	application to or removal from the probe / transducer, or during scanning per Intended Use. Ultrasound-related Product Codes ITX (the Predicate Device Group) and IYO (the Subject Device Group) do not specifically address effectiveness requirements for transducer / probe drapes. However, the functional requirements for these devices are related to those for Product Code KKX Surgical Drapes and MMP Protective Barrier Covers. ANSI/AAMI PB70:2003 "Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities" is a Recognized Consensus Standard for Product Codes KKX Surgical Drapes and MMP Protective Barrier Covers. The CFI device group's materials and heat-seals (the subject device group) were in-house-laboratory-evaluated per ANSI/AAMI PB70:2003 and determined to conform to Section 5.2.1.2 Level 1. This satisfies the 4.2.3.2 requirement that "the entire surgical drape shall have a barrier performance of at least Level 1." The predicate device group was laboratory tested under an unspecified "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." In both cases, the testing showed that the device groups were an effective barrier as required per their respective Intended Use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2009

Mr. John W. Schaefer
Regulatory Manager
Contour Fabricators, Inc.
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Re: K090773
Trade/Device Name: Various Ultrasound Probe Drapes
Regulation Number: 21 CFR 892.1560
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: IYO
Dated: July 24, 2009
Received: August 12, 2009

Dear Mr. Schaefer:

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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

contour fabricators inc.

Indications for Use

510(k) Number: K090773

Device Name: Various Ultrasound Probe Drapes

Indications for Use:

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Prescription Use --YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use--NO (Part 21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090773

1 REVISED PAGE FOR SECTION "INDICATIONS FOR USE", TO BE SUBSTITUTED FOR 1 EXISTING PAGE OF ORIGINAL SUBMISSION.

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