



SEP 23 1998

K981069

International Medical

510 (k) SUMMARY

Poly-urethane Ultrasound Transducer Cover

Date Summary Prepared: 2 october 1997

Submitter's Name: International Medical Products BV
Address: Gerritsenweg 5, 7202 BP, Zutphen, Holland
Telephone No: (+31)(0575)596500 fax: (+31)(0575)519639
Contact Person: H.G te Winkel, Product-Manager

Establishment Registration Number: 8030461

Device Trade/ Proprietary Name: Ultra-Cover® PU-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 Prococode: ITX

Description of Predicate device(s): The Ultra-Cover ® PU transducer cover is equivalent to Civco Medical Instruments legally marketed Poly Ultrasound Transducer Cover, 510(k) reference number K970513



Description of Subject Device Submitted for Premarket Notification: Ultra-Cover® PU-transducer covers provides an efficient, conformal covering to fit various & specific ultrasound transducer geometries. The cover helps prevent the transmission of pathogens from one patient to another.

Ultrasound imaging is not impaired by use of the cover as it is intended. Adequate coupling between the cover and the transducer is required transmission gel onto the transducer face or into open end of cover, inserting ultrasound transducer into closed end of cover. The removal process is a reverse method from the application.

Various sizes and shapes of covers are offered in order to customize the fit to specific transducer geometries.

Covers are packaged in both sterile and non-sterile procedure kit form for single patient/procedure, disposable use.

Product categories/models include:

General Purpose Ultra-Cover® PU-transducer covers (sterile and non sterile)
Intraoperative Ultra-Cover® PU-kits (sterile)

Intended use/ Indications for use: Protective cover placed over diagnostic ultrasound transducer/probe/scanhead instruments. The cover allows use of the transducer in scanning procedures for body surface, endocavity, and intra-operative diagnostic ultra-sound, while helping to prevent transfer of microorganisms, body-fluids, and material to the patient and healthcare worker during reuse of the transducer.

Ultra-Cover® PU-transducer covers are furnished sterile & non-sterile; single use patient/procedure, disposable.

The intended use and indications for use place Ultra-Cover® PU-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).



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

Intended Use : Both the Civco device and International Medical device is a thin, conformal protective cover system for ultrasound transducer usage in body surface, endocavity, and intra-operative patient environments helping 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; a disposable device for single use only.

Design : a 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 : The Civco device is made of poly-urethane and poly-ethylene. The International Medical device is made of poly-urethane thermoplastic film and aqueous poly-urethane suspension.

Manufacturing : manufacturing IMP device processes: - impulse heat-seal fabrication
-dipping techniques.

Manufacturing Civco device process : - impulse heat-seal fabrication

: packaging : cleanroom class 10.000

: sterilization IMP device: Gamma irradiation

sterilization Civco device: Ethylene Oxide

Manufacturing Facilities: - Medistad Holland
Nijverheidsweg 1
1670 AB Medemblik

- International Medical Products BV Lichtenvoorde
Dieselstraat 9
7131 PC Lichtenvoorde

Sterilization Facility : - Gammaster
Morsestraat 3
6716 AH Ede

Safety : materials have been biologically evaluated using biocompatibility tests for cytotoxicity acute systematic toxicity, irritation and sensitization.
Testing is in accordance with ISO 10993 Biological Evaluation of Medical Devices, executed by NamSa USA and Wickham Laboratories GB.
Ultra-Cover® PU-transducer covers 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 communication).
Testing has demonstrated subject materials/devices to be non-toxic, non-sensitizing, and non-irritating.

Effectiveness : material strength and elasticity is adequate to allow use without tearing or pinholing the cover during application and removal of cover from transducer and during scanning under intended uses.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Carole Stamp
Program Manager
International Medical Products, B.V.
c/o TÜV Product Service Inc.
1775 Old Highway 8
New Brighton, MN 55112

Re: K981069
Ultra-Cover/ Pu-Transducer Cover
Dated: September 14, 1998
Received: September 15, 1998
Regulatory class: II
21 CFR 892.1570/Procode: 90 ITX

Dear Ms. Stamp:

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 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,

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

510(k) Number (if known): _____

Device Name: _____

Indications For Use:

Protective cover placed over diagnostic ultrasound-transducer/probe/scanhead instruments. The cover allows use of the transducer in scanning procedures for body surface, endocavity, and intra-operative diagnostic ultra-sound, while helping to prevent transfer of micro-organisms, body-fluids, and material to the patient and healthcare worker during reuse of the transducer.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K981069

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)