ASCENDIA

AUG 15 2005

K050320

510(k) Summary

12 January 2005

General Information

Submitter's name:	Ascendia MedTech AB
Address:	Finlandsgatan 18, SE-164 74 Kista, Sweden
Telephone No:	+45 8 444 54 00
Contact Person:	Anders Weiland
Establishment Registration Number:	8032029
Device Trade Name:	FreeeScan® Ultrasound Transducer Cover
Device Common Name:	Ultrasound Transducer Cover/Sheath/Drape
Device Classification Name:	Diagnostic Ultrasonic Transducer
Classification:	Class II (under 21 CFR 892.1570)
Classification Panel:	Radiology
Classification Procode:	ITX
Performance Standards:	No applicable standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.

Subcontractors

Contracted Sterilizer:	Paper-Pak Sweden AB Jarnvagsgatan 34 311 22 Aneby Sweden Phone No. +46 380-475 00 Contact Name: Rickard Thorsen
Manufacturer:	Nolato Medevo AB 260 93Torekov Sweden Phone No. +46 431-44 22 90 Contact Name: Henrik Rosengren

Repackager:

TotalLogistik
Box 143
311 22 Falkenberg
Sweden
Phone No. +46 34-62 94 30

Contact Name: Jan Lindman

Device Description

The FreeeScan® Ultrasound Transducer Cover provides a thin, conformal covering to fit various ultrasound transducer geometries. The device is manufactured as a one-piece design that provides a covering to prevent the transmission of pathogens, as the ultrasound transducer is reused from one patient to another.

The cover material is Chloroprene (synthetic rubber), which is similar to the non-latex material used in medical examination gloves or surgical gloves. Type I natural latex allergy does not occur in response to Chloroprene since the synthetic rubber does not contain the natural protein allergen which is present in latex.

Various sizes and shapes of covers are offered in order to fit different transducer geometries. The following product models are currently included (other shapes are likely to be added):

- FreeeScan® 1 - W:3.4 cm, L:45-244 cm (Drawing 5500-000002-1B)
- FreeeScan® 4 - W:10 cm, L:45-244 cm (Drawing 5500-000003-1B)
- FreeeScan® 6 - W:9.5/11.5 cm, L:45-244 cm (Drawing 5500-000004-1B)
- FreeeScan® 8 - W:7.5 cm, L:45-244 cm (Drawing 5500-000005-1B)
- FreeeScan® 77 - Ø:2.6 cm, L:30 cm (Drawing 5500-000016-1A)
- FreeeScan® 84 - Ø:3 cm, L:30 cm (Drawing 5500-000015-1A)

All of these versions are composed of the same materials, they are made using the same processes and procedures, in the same facilities and on the same equipment.

Intended Use of the Device

The FreeeScan® Ultrasound Transducer Covers are protective covers applied to ultrasound transducers. These covers are designed to provide a sterile barrier between the non-sterile TXD's (and instrument guide adapters in some cases) and the patient/healthcare worker. The covers are intended for use during both sterile and non-sterile procedures using sector, linear, intravaginal and rectal transducers.

The cover is latex-free and therefore beneficial in procedures with a patient with known type I hypersensitivity, or for the healthcare worker who has become type I sensitive. The transducer covers are supplied sterile or non-sterile and intended for single-use.

Covers are packed in sterile or non-sterile "convenience" kits form for single patient/procedure, disposable use. Covers kits are supplied with needle guide devices, coupling gel packet, elastic bands, and tape.

Predicate Device

Ascendia MedTech AB believes that the FreeeScan® Ultrasound Transducer Cover is substantially equivalent to the CIVCO Medical's ultrasound transducer cover, NeoFlex™ Ultrasound Transducer Cover.

Predicate Device	510(k) Reference	Manufacturer
NeoFlex™ Ultrasound Transducer Cover	K991236	CIVCO Medical, Inc, Kolona, IA, USA

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VAT NO. SE556236922201 . REG. NO. 556-236 9222. REGISTERED OFFICE: KISTA.

Substantial Equivalent Summary

Ascendia MedTech AB believes that the FreeeScan® Ultrasound Transducer Cover is substantially equivalent in safety and effectivness to the CIVCO Medical NeoFlex™ Ultrasound Transducer Cover. The following comparison table shows this substantial equivalence:

Parameter	FreeeScan® Ultrasound Transducer Cover	NeoFlex™ Ultrasound Transducer Cover
Intended Use/Indications for Use	Same	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 micro organisms, 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. Is non-latex therefore beneficial when treating a patient with known type I hypersensitivity, or for the healthcare worker who has become type I sensitised.
Design	The FreeeScan® Ultrasound Transducer Cover is folded. In other respects the same.	One-piece, closed end, rolled (condom style) with various dimensional configurations necessary to accommodate differences in ultrasound transducer geometries.

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Parameter	FreeeScan® Ultrasound Transducer Cover	NeoFlex™ Ultrasound Transducer Cover
Material	Same	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	Packaged in class 100 000 clean room, otherwise the same.	Dip-molding/rubber vulcanisation Packaged in class 10 000 clean room per Federal Std 209e. Packaging system per ANSI/AAMI/ISO 11607
Quality System	Same	FDA/QSR cGMP 21CFR Part 820. ISO 9001/ISO 13485/EN 46001
Sterility	Same	Sterilization (when applicable) by 100%EtO method; Validated ANSI/AAMI/ISO 11135 SAL 10^{-6}

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Parameter	FreeeScan® Ultrasound Transducer Cover	NeoFlex™ Ultrasound Transducer Cover
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 cytoxicity, irritation, sensitisation, and ethylene oxide sterilization residuals have demonstrated the FreeeScan® chloroprene material/cover device is: Severely cytotoxic Non-sensitizing Non-irritating 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 chloroprene synthetic rubber.	Biocompatibility tests for acute systemic toxicity, irritation, sensitisation, 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.

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Parameter	FreeeScan® Ultrasound Transducer Cover	NeoFlex™ Ultrasound Transducer Cover
Effectiveness	The FreeeScan® Ultrasound Transducer Cover has a nominal thickness of 0.2 mm. The FreeeScan® Ultrasound Transducer Cover provides an effective barrier to prevention of microbial migration. In other respects the same.	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 pin holing 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 .0065" Does not impair ultrasound imaging NeoFlex™ polychloroprene transducer cover provides an effective barrier to 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 blood borne pathogens using viral penetration as a test system. Polychloroprene (neoprene) material is used for medical examination/surgical gloves.

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Conclusion

Ascendia MedTech AB believes that this premarket notification submission for FreeeScan® Ultrasound Transducer Cover has demonstrated Substantial Equivalence as defined and in accordance with the Federal Food, Drug and Cosmetic act and various guidance documents issued by the Center for Device and Radiological Health.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2005

Ascendia MedTech AB
% Ms. Jane B. Campbell
President
J & D Campbell Associates, Inc.
485 LaRoe Road
CHESTER NY 10918

Re: K050320
Trade/Device Name: FreeeScan® Ultrasound Transducer Cover
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: August 2, 2005
Received: August 3, 2005

Dear Ms. Campbell:

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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 (21 CFR Part 807); 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 Section 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 the labeling regulation, please contact the Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). 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) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David C. Ayerson

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

Enclosure

1 Statement of Indications for Use

Device name: FreeeScan® Ultrasound Transducer Cover

1.1 Indications for Use

The FreeeScan® Ultrasound Transducer Covers are protective covers applied to ultrasound transducers. These covers are designed to provide a sterile barrier between the non-sterile transducer (and instrument guide adapters in some cases) and the patient/healthcare worker. The covers are intended for use during both sterile and non-sterile procedures using sector, linear, intravaginal and rectal transducers.

The cover is latex-free and therefore beneficial in procedures with a patient with known type I hypersensitivity, or for the healthcare worker who has become type I sensitive.

The transducer covers are supplied sterile or non-sterile and intended for single-use.

Prescription use ✓

David A. Lagrow

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050320