K033559

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IneedMD – ILC Dover
12-Lead Glove
510(k) Summary

Scope

The scope of this document is limited to the IneedMD 12-Lead Glove, a Class II medical device.

Device Description

The 12-Lead Glove has been designed to obtain an electrocardiogram (ECG) with pre-positioned electrodes affixed to the underside of a glove-like sheath. The pre-printed conductive circuitry is contained within the sheath (or shell) on a flexible substrate. To obtain the tracing, the operator need only connect the glove via a single (multi-conductor) cable connected to the ECG monitor, slip on the glove, position their hand on the patient's chest, and attach three extendable electrodes which will provide a full 12-Lead recording. The 12-Lead Glove saves valuable time required for set-up compared to the standard approach with multiple electrode placements. It eliminates the confusion of working with the standard cables and eliminates erroneous ECG readings.

Component/Material Descriptions

The 12-Lead Glove is made up of several components, or sub-assemblies. They include:

- the shell, or the glove-like sheath which has indirect contact with the patient's skin
- the electrodes (and electrode foam backers) which are embedded within the shell and has direct contact with the patient's skin
- the pre-printed conductive flex-circuit (and extendable limb leads), have no contact with the patient's skin
- the ECG Connector Cable to transmit the electrical impulses to an ECG machine

The following tables delineate all materials used in the 12-Lead Glove, and demonstrate their safety and acceptability for use in this device. Most materials used either have predicate device history or are currently used in pre-approved medical devices.

Shell

Component Description	Material(s)	End-Product Processing	Acceptability for Use (Predicate Device and/or 510K if available)
- multi-layered glove like sheath - incidental contact with patient's skin - direct contact with operator's skin	- 100% polypropylene fiber - spunbond nonwoven fabric - manufactured without lubricants/finishes - latex and powder free	- layers thermally weld to create the glove-like structure	currently used pre-approved devices, - Class I Hygienic products (incontinent pads, adult/infant diapers, tampons) - Class II Protective Apparel (gowns, surgical facemasks*) - USP Class VI Implantable Devices (hernia repair mesh, sutures **K002999**)

* Guidance for Industry and FDA Staff; Surgical Masks – Premarket Notification [5109k)] Submissions, Document Issued 3/5/2004Center for Devices and Radiological Health, page 6.

The polypropylene fabric has demonstrated exceptional performance in biocompatibility tests, AAMI/ISO 10993-5, Cytotoxicity – Agar Diffusion and AAMI/ISO 10993-10, Primary Dermal Irritation in Rabbits.

Test Results are included in Attachment I of this document.

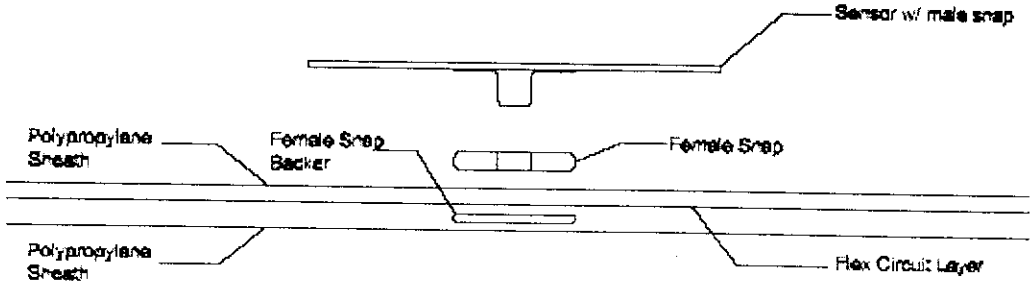
Electrodes and Electrode Backers

Component Description	Material(s)	End-Product Processing	Acceptability for Use (Predicate Device and/or 510K if available)
Electrodes			
- Kendall MediTrace 230 (ECG Conductive Adhesive Electrodes)	- conductive hydrogel - adhesive-backed foam - snap attachment	- electrode is affixed (crimped) to glove sheath - snap 70/30 brass, nickel plated, 0.005" thick - has no contact with patient	- Medi-Trace 200 and Medi-Trace 200-30* **K960968**
Electrode Backers			
- Scapa BioFlex® RX416VSa	- white polyethylene foam - double coated with a medical-grade acrylic pressure sensitive adhesive	- affixed underneath the electrode to provide stability of the electrode for ease of placement - does not contact the patient nor the operator's skin	- product safety sheet lists the Class II tests performed and passed - cytotoxicity - primary skin irritation - sensitization - also contains no natural latex proteins

* Each of the pre-approved electrodes have received FDA approved biocompatiblity and EC12-1991 and EC12-1991 AAMI Standards.

The electrodes are installed to the glove sheath by crimping. They function through contact with the printed conducting pad of the flex-circuit.

Figure 1: Schematic of the electrode affixed to the sheath



Flex-Circuit Layer

Component Description	Material(s)	End-Product Processing	Acceptability for Use (Predicate Device and/or 510K if available)
Flexible Circuit Substrate			
- flexible substrate, 3-6 mils thick	- 100% polyester substrate - conductive silver ink, topped with carbon ink to expose pads and traces covered with dielectric (insulating) ink	- the pre-printed circuit receives no additional processing and is positioned within the layers of the glove and away from direct contact with the patient	- Uni-Lead™ Sensor Arrays **K932903**
Pre-printed Conductive Tracings			

- pre-printed and cured conductive tracings	- pre-printed and cured circuitry
	  - conductive silver ink
	  - carbon ink
	  - insulating ink
		- manufacture of the end-item does not change or affect the pre-printed tracings	- Uni-Lead™ Sensor Arrays **K932903**

Extendable Limb Leads			

- three extendable limb leads are made from the same materials found in the flex circuit	- 100% polyester substrate
	- pre-printed circuitry
	  - conductive silver ink
	  - carbon ink
	  - insulating film
		- the extendable leads are positioned within the layers of the glove when not in operation and pulled into use for operation. Direct skin contact is possible	- Uni-Lead™ Sensor Arrays **K932903**

Attached to this document in Attachment II, are comparisons schematic drawing/photo of the proposed and predicate flex-circuits.

ECG Cable and Connector

Component Description	Material(s)	End-Product Processing	Acceptability for Use (Predicate Device and/or 510K if available)
- Medical Cables, Inc. connecting cable with an ABS connector **K002781**	- 10 conductor shielded cable - PVC insulated - Connector will contain a rigid circuit board	- the ECG connector cable is not attached during manufacture and therefore not effected by any processing measures	- Kendall Tronomate **K952659** - Merit Industries **K942321**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2004

INeedMD
c/o Irving Wiesen, Esq.
Law Offices of Irving L. Wiesen
860 Canal Street
Stamford, CT 06902

Re: K033559
Trade Name: 12-Lead Glove
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph electrode
Regulatory Class: II (two)
Product Code: DRX
Dated: September 22, 2004
Received: September 24, 2003

Dear Mr. Wiesen:

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 such 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); 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 our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K033559**

Device Name: **12 Lead glove**

Indications For Use: The 12 lead glove is designed to configure ECG electrodes in a single unit using a conventional ECG electrode configuration for the purpose of conducting an electrocardiogram. It is for use in patients with a chest girth of 97 - 104 cm.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K033559