K121335

5. 510(k) SUMMARY
[per 21 CFR 807.92]

SEP 13 2012

5.1 Submitter Information

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Contact Name: Dr Raffi Krikorian, Ph.D

Date of summary: August 28, 2012

5.2 Device Identification

Trade name: G-Derm™ Powder Free Surgical Glove made of styrene-ethylene/butylene-styrene (SEBS) and styrene-ethylene/propylene-styrene-ethylene/propylene (SEPSEP) synthetic copolymers

Common name: Surgical glove
Classification name: Surgeon's glove

Product Code: KGO
Regulation number: 21 CFR 878.4460
Device Class: Class I (general controls)

5.3 Identification of Predicate Devices

- Elastyfree by ECI Medical Technologies Inc (K020918)
- Safeskin Tactylon PF powder-free surgical gloves (K994081)
- Tactylon by Tactyl Technologies (K955419)

5.4 Device Description

The G-Derm™ Powder Free Surgical Glove is made of a blend of styrene-ethylene/butylene-styrene (SEBS) and styrene-ethylene/propylene-styrene-

ethylene/propylene (SEPSEP) synthetic copolymers. It is coated with a polyurethane based coating on the inner side to facilitate donning.

5.5 Indications for Use

The G-Derm™ Surgical Glove is a disposable sterile powder-free medical device made of styrene-ethylene/butylene-styrene (SEBS) and styrene-ethylene/propylene-styrene-ethylene/propylene (SEPSEP) synthetic copolymers that is intended to be worn by operating room personnel to protect a surgical wound from contamination.

5.6 Comparison to Predicate Devices

	G-Derm™	Elastyfree	Safeskin Tactylon	Tactylon
Regulation No.	21 CFR 878.4460	21 CFR 878.4460	21 CFR 878.4460	21 CFR 878.4460
Device Class	Class I	Class I	Class I	Class I
Technology	Solvent borne material	Solvent borne material	Solvent borne material	Solvent borne material
Patient contacting physical barrier material	Styrenic thermoplastic elastomers	Styrenic thermoplastic elastomers	Styrenic thermoplastic elastomer	Styrenic thermoplastic elastomer
User contacting physical barrier material	Styrenic thermoplastic elastomers with a polyurethane coating	Styrenic thermoplastic elastomers with a polyurethane coating	Styrenic thermoplastic elastomers with a polymer coating	Styrenic thermoplastic elastomer
Standards met	ASTM D3577 ASTM D5151 ASTM D6124	ASTM D3577 ASTM D5151 ASTM D6124	ASTM D3577 ASTM D5151 ASTM D6124	ASTM D3577 ASTM D5151 ASTM D6124
Sterilization	Sterile (SAL 10^{-6}). Gamma irradiation	Sterile (SAL 10^{-6}). Gamma irradiation	Sterile. Gamma irradiation	Sterile. (method unknown)

5.7 Performance Data

The G-Derm™ Surgical Glove possesses the following technological characteristics:

Characteristics	Standard
Thickness: 0.21 ±0.02 mm	Meets ASTM D3577
Length: 280 mm min.	Meets ASTM D3577
Physical Properties	Meets ASTM D3577,

	Type 2
Powder Free: less than 2 mg per glove	Meets ASTM D6124
Freedom from holes: AQL 0.25	Meets ASTM D5151
Sterility: SAL 10^{-6}	ISO 11737
Biocompatibility: *In Vitro Cytotoxicity: Passes* *Acute Systemic Toxicity in Mice: Passes* *Primary skin irritation in Rabbits: Passes* *Guinea Pig Maximization Sensitization: Passes*	ISO 10993-1 ISO 10993-5 ISO 10993-11 ISO 10993-10 ISO 10993-10

5.8 Clinical Data

Clinical data is not needed for medical glove 510(k) submissions.

It can be concluded that the G-Derm™ Surgical Glove will perform according to the performance standards referenced above, FDA requirements and the labeling claims for this product. Consequently, this device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SEP 13 2012

Hutchinson Santé S.N.C.
Dr. Raffi Krikorian
Vice President Science & Regulatory
Rue Marret et Paturel
Liancourt, France F-60140

Re: K121335
Trade/Device Name: G-Derm™ Powder Free Surgical Glove made of Styrene-Ethylene/Butylene-Styrene (SEBS) and Styrene-Ethylene/Propylene-Styrene-Ethylene/Propylene (SEPSEP) Synthetic Copolymers
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: August 28, 2012
Received: August 29, 2012

Dear Dr. Krikorian:

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 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,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____K121335_____

Device Name: G-Derm™ Powder Free Surgical Glove made of styrene-ethylene/butylene-styrene (SEBS) and styrene-ethylene/propylene-styrene-ethylene/propylene (SEPSEP) synthetic copolymers

Indications for Use:

The G-Derm™ Surgical Glove is a disposable sterile powder-free medical device made of styrene-ethylene/butylene-styrene (SEBS) and styrene-ethylene/propylene-styrene-ethylene/propylene (SEPSEP) synthetic copolymers that is intended to be worn by operating room personnel to protect a surgical wound from contamination.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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