APR 13 2005 K050187

Section E – 1 - 510(k) Summary

Submitters Name : Medigloves Ltd.

Submitter's Address : 33/3 Moo 2 Tivanont Road Amphur Muang Pathumtani 12000 Thailand

Submitter's Phone Number : +662 501 2141-5

Submitter's Fax Number : +662 501 2146-7

Name of Contact Person : Mr. Worasak Wongprakornkul

Date of Preparation : January 19, 2005

Trade Name of Device : Medigloves® Sterile Powder-free Synthetic Polyisoprene Surgical Gloves

Device Name : Medigloves® Sterile Green Powder-free Synthetic Polyisoprene Surgical Gloves (Green)

Common Name : Surgical Gloves

Classification Name : Surgeon's gloves, powder-free (per proposed § 878.4461)

Legally Marketed Device to Which Equivalency is Being Claimed :

Medigloves® Sterile Powder-free Synthetic Polyisoprene Surgical Gloves as described in this 510(k) notification are substantially equivalent to:

ESTEEM® Sterile Polyisoprene Surgical Gloves (K011721)
Sterile SensiCare™ Synthetic Polyisoprene Powder-Free Surgical Gloves (K002933)
BarrierPlus® Powder-Free Synthetic Polyisoprene Surgical Gloves (K990710)

The difference is that Medigloves' gloves has green color but the safety and effectiveness of the device is maintained.

Description of the Device:

The gloves are made of polyisoprene synthetic latex and green colored. They are washed with Ammonia solution to leach off mold release powder, chemical and protein before they are chlorinated and inner coated with the solution of coating material for ease of donning. The gloves are tested for pinhole by water leak test machine. They are sterilized by gamma irradiation.

Medigloves® Sterile Powder-free Synthetic Polyisoprene Surgical Gloves meet the description of Rubber Surgical Gloves as described in ASTM D 3577-01a$^{\varepsilon 2}$, type 2 rubber surgical gloves.

Section E – 2 – 510(k) Summary (continued)

Intended Use of the Device:

Medigloves® Sterile Powder-free Synthetic Polyisoprene Surgical Gloves is a disposable device made of synthetic material that may bear trace amount of glove powder and is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contamination.

Summary of Technological Characteristics Compared to the Predicate Device:

Medigloves® Sterile Powder-free Synthetic Polyisoprene Latex Surgical Gloves posses the following technological characteristics (as compared to ASTM or equivalent standards).

Dimensions : Meets ASTM D3577-01a$^{\varepsilon 2}$

Physical Properties : Meets ASTM D3577-01a$^{\varepsilon 2}$

Freedom from pinholes : Meets ASTM D3577-01a$^{\varepsilon 2}$
Meets ASTM D5151-99

Powder-Free : Meets ASTM D6124-01
2 mg/glove maximum

Sterility : Meets ASTM D3577-01a$^{\varepsilon 2}$

Brief Discussion of Nonclinical Tests :

Primary irritation testing in the rabbits and sensitization testing on the mice indicate no irritation or sensitization.

Brief Discussion of Clinical Tests :

Clinical data are not needed for surgical gloves.

Conclusions Drawn for the Nonclinical and Clinical Tests :

Nonclinical laboratory and animal data indicate that Medigloves® Sterile Powder-free Synthetic Polyisoprene Surgical Gloves meets all performance and biocompatibility requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2005

Medigloves Limited
C/O Mr. Kobby Dankwah
Medigloves Representative
Westminster Capital, Incorporated
9665 Wilshire Boulevard, Suite M-10
Beverly Hills, California 90212

Re: K050181
Trade/Device Name: Medigloves® Sterile Powder-Free Synthetic Polyisoprene Surgical Gloves (Green)
Regulation Number: 878.4460
Regulation Name: 878.4460
Regulatory Class: II
Product Code: KGO
Dated: January 26, 2005
Received: January 31, 2005

Dear Mr. Dankwah:

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.

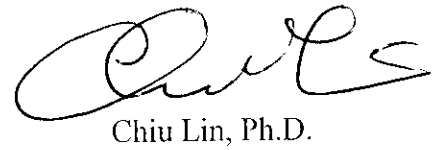
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section D-1 – Statement of Indications for Use

Indications for Use

510(k) Number (if known) : K050181

Device Name : Medigloves® Sterile Powder-free Synthetic Polyisoprene Surgical Gloves (Green)

Indications For Use:

A powder-free surgeon's glove is a disposable device made of synthetic material that may bear a trace amount of glove powder and is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

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

510(k) Number: K050181

Prescription Use (Part 21 CFR 801 Subpart D) ✓ AND/OR Over-The-Counter (21 CFR 807 Subpart C) NO ✓

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

Concurrence of CDRH, Office of Device Evaluation (ODE)