

K071700

510(k) SUMMARY

1. Applicant: Mölnlycke Health Care US, LLC
5550 Peachtree Parkway Suite 500
Norcross, GA 30092
2. Contact Person: Steven Dowdley, RAC
Director of Regulatory Affairs
Tel.: 678-250-7930
Fax: 678-250-7979
- or
- MKA Consulting
Marcia K. Ash, RAC
Tel.: 404-906-0492
3. Device Name: Biogel® Sensor™ Surgeon's Glove with non-pyrogenic statement
Common Name: Surgical Glove (CFR 878.4460)
Classification: Class I
4. Predicate Device : K053443 - Eclipse, Non-pyrogenic, Latex, Powder-free, Glove
5. Device Description: The Biogel® Sensor™ Surgeon's Glove is a sterile powder free, polymer coated latex surgical glove. The glove contains 50 micrograms or less of total water extractable protein per gram.
6. Intended Use of the Device: The Biogel® Sensor™ Surgeon's Glove is a disposable device made of natural rubber latex that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.
7. Technological Characteristics of the Device: The Biogel® Sensor™ Surgeon's Glove characteristics are summarized below as compared to ASTM requirements and to the predicate devices.
- | <u>Characteristic</u> | <u>Standard</u> |
|---|-------------------|
| Dimensions | Meets ASTM D3577 |
| Physical Properties | Meets ASTM D3577 |
| Freedom from Holes | Meets ASTM D3577 |
| Biocompatibility | Meets ISO 10993-1 |
| LALTest - final endotoxin concentration | ≤ .50 EU/ml |
8. Performance Data The performance data are summarized above.
9. Clinical Data No clinical data was required.
10. Conclusion: The Biogel® Sensor™ Surgeon's Glove meets the technological characteristics of ASTM D3577 and is substantially equivalent to the predicate devices cited in this 510(k) summary.

SEP 11 2007



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Steven Dowdley
Director of Regulatory Affairs
Molnckce Healthcare, US LLC
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

SEP 11 2007

Re: K071700

Trade/Device Name: Biogel Sensor, Latex Surgeon's Glove with Non-pyrogenic
Claim and Protein Content Labeling Claim (50 micrograms or less)

Regulation Number: 878.4460

Regulation Name: Surgeon's Glove

Regulatory Class: I

Product Code: KGO

Dated: August 22, 2007

Received: August 27, 2007

Dear Mr. Dowdley:

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

Indication for Use

510(k) Number:
K071700

Device Name:
Biogel Sensor, Latex Surgeon's Glove with Non-pyrogenic Claim and Protein Content Labeling Claim (50 micrograms or less)

Indication For Use:
The Biogel® Sensor™ Surgeon's Glove is a sterile disposable device made of natural rubber latex that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

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



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

510(k) Number: K 071700

Concurrence of CDRH, Office of Device Evaluation