

K071465

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
3. Device Name: Biogel Orthodeaptic Surgical Glove with non-pyrogen statement
Common Name:
Classification: Surgical Glove (CFR 878.4461)
Class I
4. Predicate Device : K980516 - Biogel Orthodaepic Surgical Glove
K060030 - Eclipse, Non-pyrogenic, Latex, Powder-free, Glove
5. Device Description: The Biogel Orthodeaptic Surgical 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 Orthodaepic Surgical 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 Orthodaepic Surgical 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 | <0.25EU/ml |
8. Performance Data The performance data are summarized above.
9. Clinical Data No clinical data was required.
10. Conclusion: The Biogel Orthodaepic Surgical Glove meets the technological characteristics of ASTM D3577 and is substantially equivalent to the predicate devices identified in sited in this 510(k) summary.

SEP 11 2007



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2007

Mr. Steven Dowdley, RAC
Director of Regulatory Affairs
Mölnlycke Health Care US, LLC
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

Re: K071465

Trade/Device Name: Biogel Powder-Free Orthopedic Latex Surgical Glove,
with Protein Content Labeling Claim (50 micrograms or less) &
with Non-Pyrogenic Claim

Regulation Number: 21 CFR 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 (240) 276-3150 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



Molnlycke Heath Care US, LLC
5550 Peachtree Parkway, Suite 500
Norcross, GA. 30092

3.0 Indications for Use Statement:

Applicant: Molnlycke Heath Care US, LLC
510(k) Number: K071465
Device Name: Biogel Powder-Free Orthopedic Latex Surgical Glove, with Protein Content Labeling Claim (50micrograms or less) & with Non-Pyrogenic Claim

Indication for Use:

The Biogel Orthopedic 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.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ Or Over-The-Counter X
Per 21 CFR 801.109

510(k) Number:

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

K071465

Shelley R. Murphy MD