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

K081180

AUG 26 2008

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: Common Name: Classification:	Skinsense Polyisoprene Underglove Surgical Glove (CFR 878.4461) Class I
4.	Predicate Device : Device Description:	The Skinsense Polyisoprene Underglove 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 Skinsense Polyisoprene Underglove 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 Skinsense Polyisoprene Underglove characteristics are summarized below as compared to ASTM requirements and to the predicate devices.

Characteristic	Standard
Dimensions	Meets ASTM D3577
Physical Properties	Meets ASTM D3577
Freedom from Holes	Meets ASTM D3577
Biocompatibility	
Cytotoxiciity Study	Pass
ISO Skin Irritation Study	Pass
LAL Test	<0.25EU/ml.

8.	Performance Data	The performance data are summarized above.
9.	Clinical Data	No clinical data was required.
10.	Conclusion:	The Skinsense Polyisoprene Underglove meets the technological characteristics of ASTM D3577-01-ae2 and is substantially equivalent to the predicate devices identified in sited in this 510(k) summary.

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
Mölnlycke Health Care US, LLC
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

AUG 2 6 2008

Re: K081180
Trade/Device Name: Skinsense Polyisoprene Underglove
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO
Dated: August 13, 2008
Received: August 15, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-*0115*. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

INDICATION FOR USE

Applicant: Molnlycke Heath Care US, LLC

510(k) Number:

Device Name: Skinsense Polyisoprene Underglove

Indication for Use:

The Skinsense Polyisoprene Underglove is a disposable device made of non-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

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

510(k) Number: K081180