510(k) Summary

K060030

1. Owner Information:

BioBarrier, Inc.
12104 Bonny Lane
Los Angeles, CA 90049
Phone: 310-472-7170

JUN 27 2006

Contact: David W. Mullis, Jr., Ph.D., RAC
Telephone: 779-207-9174
FAX: 770-207-7682

Date: December 30, 2005

2. Trade Name: The Double™ Glove
Common Name: Surgical Glove
Classification: Surgeon's Glove 21CFR878.4461
Code: 79KGO

3. Predicate Device:
-Class I Surgeon's Gloves, Powder-free
-Meets all ASTM D 3577 requirements
-Predicate: K033564, Kanam Latex Industries Powder-free Latex Surgeon's Gloves Polymer Coated Sterile Contains 50 micrograms or less of total water extractable protein per gram

4. Device Description: The Double™ Glove, a Single-Donning™ Double Glove with 2 Discrete Layers Fused at the Wrist. A Class I, Powder-free, Polymer Coated, Latex Surgeon's Glove

5. Intended Use: The powderfree, polymer coated, sterile surgeon's glove is a disposable device made of natural rubber latex that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

6. Technological Characteristics: The Double™ Glove characteristics are summarized below compared to ASTM requirements and to the predicate device.

Characteristic	Standard
Dimensions	Meets ASTM D 3577
Physical Properties	Meets ASTM D 3577, Type I
Freedom from Holes	Meets ASTM D 3577
Biocompatibility:	
Primary Skin Irritation (Rabbits)	Pass
Guinea Pig Sensitization	Pass

7. Performance Data: The performance data are the same as summarized in No. 6, above.

8. Clinical Data: Clinical data not required.

9. Conclusions: The Double™ Glove meets the technological characteristics of ASTM D 3577 and is substantially equivalent to the predicate device and Class I, powder-free, latex surgeon's gloves with a less than 50 microgram/gram of water extractable protein claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2006

Biobarrier, Incorporated
C/O Dr. David W. Mullis
Mullis & Associates, Incorporated
367 Pleasant Valley Road
P.O. Box 39
Good Hope, Georgia 30641

Re: K060030
Trade/Device Name: Powder-Free, Polymer Coated, Sterile, Single Donning Double Layer, Surgeon's Glove Contains 50 Micrograms or Less of total Water Extractable Protein Per Gram
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: June 5, 2006
Received: June 6, 2006

Dear Dr. Mullis:

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

Indications for Use

510(k) Number (if known): K060030

Applicant: BioBarrier, Inc.

Device Name: Powder-free, polymer coated, sterile, single donning double layer, surgeon's glove contains 50 micrograms or less of total water extractable protein per gram.

Indications for Use: The powder-free, polymer coated, sterile surgeon's glove is a disposable device made of natural rubber latex that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

Prescription Use_____ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature] 4/27/06

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

510(k) Number K060030