3/12/99

K982600

WEMBLEY RUBBER PRODUCTS (M) SDN BHD (No: 147817-V)

Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, Malaysia.
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ATTACHMENT 3

CONTACT PERSON : Y. W. CHOW

510(k) SUMMARY

1. **Trade Name** : PROFEEL SYNTHETIC COPOLYMER SURGICAL GLOVES (POWDERED)

2. **Common Name** : Surgeon's Gloves

3. **Classification Name** : Surgeon's Glove

4. **Substantial Equivalence** :

   Class I synthetic surgeon's glove, 79 KGO, powdered. It is a styrene-butadiene block copolymer glove. The device is identical, and substantially equivalent to the Elastyren Surgical Glove manufactured by ECI Medical Technologies Inc., Canada. It meets all of the requirements of ASTM standard D3577-91 Type 2.

5. **Description of Device** :

   Class I synthetic surgeon's glove, 79 KGO, powdered. It is a styrene-butadiene block co-polymer glove. The device is identical, and substantially equivalent to the Elastyren Surgical Glove manufactured by ECI Medical Technologies Inc., Canada. It meets all of the requirements of ASTM standard D3577-91 Type 2.

6. **Intended Use of Device** :

   The gloves are intended to be worn on the hand of healthcare personnel, operating room personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment.

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Performance data of gloves to ASTM D 3577-91 Type 2 and FDA 1000 ml watertight test.

TEST	ASTM D 3577-91 Type 2	PROFEEL Synthetic Copolymer Surgical Gloves (Powdered) - refer to Attachment 7 of Device Test Report of Compliance
1. Watertight (1000 ml)	S-4, AQL 1.5	Pass based on 1) Single Sampling Plan, S-4, AQL 1.5, 2) Multiple Sampling Plan, GII, AQL 2.5
2. Length (mm)		
Size 6½	min 265	301
7	min 265	299
7½	min 265	298
8	min 265	301
8½	min 265	303
3. Palm Width (mm)		
Size 6½	83 ± 6	85
7	89 ± 6	92
7½	95 ± 6	96
8	102 ± 6	104
8½	108 ± 6	110
4. Single Wall Thickness (mm)		
Finger	min 0.10	0.27
Palm	min 0.10	0.25
Cuff	min 0.10	0.20
5. Physical Properties Type 2		
Before Aging :		
Tensile Strength (MPa)	min 17	19.62
Ultimate Elongation (%)	min 650	1108
Stress at 500% Elongation (MPa)	max 7.0	1.92
After Aging :		
Tensile Strength (MPa)	min 12	16.35
Ultimate Elongation (%)	min 490	1101

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8. **Substantial Equivalence based on Assessment of Non-Clinical Performance Data**

The performance test data of device as shown above indicate that this glove meets requirements of ASTM D 3577-91 Type 2.

9. **Conclusion**

This glove exceeds the ASTM D 3577-91 Type 2 requirements, and also meet FDA requirements for waterleak test on pinhole AQL.

Date Summary Prepared : July 16, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 1999

Mr. Yue Wah Chow
Vice President QA/RA
Wembley Rubber Products (M) Sdn. Bhd.
Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru
Salak Tinggi, 43900 Sepang, Selangor Darul
Ehsan, MALAYSIA

Re: K982600
Trade Name: Profeel Synthetic Copolymer Surgical Gloves (Powdered)
Regulatory Class: I
Product Code: KGO
Dated: January 6, 1999
Received: January 11, 1999

Dear Mr. Yue Wah Chow:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2

Applicant : Wembley Rubber Products (M) Sdn. Bhd.

510(k) Number (if known) : K982600

Device Name : PROFEEL SYNTHETIC COPOLYMER SURGICAL GLOVES (POWDERED)

Indications For Use :

1. The surgeon's glove is a device made of synthetic copolymer intended to be worn by surgeons and/or operating room personnel to protect a surgical wound from contamination.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __________ **OR** **Over-The-Counter Use**__________
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K982600