



DEC 17 2003

510(k) SUMMARY

K032942

1.0 Submitter:

Name: WRP Asia Pacific Sdn Bhd
Address: Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA
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Date of Summary Prepared: **16 SEP 2003**

2.0 Contact Person:

Name: Mr. Terence Lim
Phone No.: +60 3 8706 1486
Fax No.: +60 3 8706 1485

3.0 Name of the device:

Trade Name: 1. Profeel, and
2. Multiple or Customer's Trade Name
Device Name: Powder Free, Polymer Coated Polyisoprene Surgical Glove, Sterile
Common Name: Surgical Gloves
Classification Name: Surgeon's Gloves (per 21 CFR 878.4460)

4.0 Identification of The Legally Marketed Device:

Class I Powder Free Synthetic rubber latex surgeon's gloves, 79KGO, that meets all the requirements of ASTM standard D 3577 – 01a^{E2} Type 2 and FDA 21 CFR 800.20.

5.0 Description of The Device:

The Powder Free, Polymer Coated Polyisoprene Surgical Glove, Sterile, meets all the requirements of ASTM standard D 3577 – 01a^{E2} and FDA 21 CFR 800.20.



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6.0 Intended Use of the Device:

The Powder Free, Polymer Coated Polyisoprene Surgical Glove, Sterile, is made of synthetic rubber latex 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.

7.0 Summary of The Technological Characteristics of The Device:

The Powder Free, Polymer Coated Polyisoprene Surgical Gloves, Sterile, are summarized with the following technological characteristics compared to ASTM or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	ASTM D 3577 – 01a ^{F2}	Meets
Physical Properties	ASTM D 3577 – 01a ^{E2}	Meets
Freedom from pinholes	ASTM D 3577 – 01a ^{F2} FDA 21 CFR 800.20	Meets
Powder-Free	ASTM D 6124 – 01	Meets < 2 mg/glove
Biocompatibility	Primary Skin Irritation in Rabbits	Passes (Not a primary skin irritant)
	Dermal Sensitization	Passes (Not a contact sensitizer)

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.



9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

10.0 Conclusion

It can be concluded that the Powder Free, Polymer Coated Polyisoprene Surgical Glove, Sterile will perform according to the glove performance standards referenced in section 7 above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Terence Lim
Associate Manager, Quality Assurance Regulatory Affairs
WRP Asia Pacific Sdn Bhd
Lot 1, Jalan 3, Kawasan Perusahaan
Bandar Baru Salak Tinggi
43900 Sepang, Selangor Darul Ehsan
MALAYSIA

Re: K032942

Trade/Device Name: Profeel and Multiple Customer's Trade Names, Powder Free,
Polymer Coated Polyisoprene Surgical Gloves, Sterile
Regulation Number: 878.4460
Regulation Name: Surgeon's Gloves
Regulatory Class: I
Product Code: KGO
Dated: September 16, 2003
Received: September 22, 2003

Dear Mr. Lim:

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 (301) 594-4618. 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/dsma/dsmamain.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

Applicant: WRP Asia Pacific Sdn Bhd

510(k) Number (if known): K032942

Device Name: PROfeel and Multiple Customer's Trade
Names POWDER FREE, POLYMER COATED
POLYISOPRENE SURGICAL GLOVES,
STERILE

Indications For Use:

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

Martha T. O'Loon

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

510(k) Number: K032942

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter ✓