BPG **BEST PUTRA GLOVES SDN.BHD.** (580515-T)
Lot 1357 & 1358, Jln Kg. Mohd Taib, Kawasan Perindustrian Sg. Choh
48000 Rawang, Selangor Darul Ehsan, Malaysia.
Tel: +03-6092 1042, +03-6092 1142 Fax: +03-6091 2820
E-mail : bpg@streamyx.com Website : www.bpgloves.com

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510 (K) SUMMARY

NOV 10 2010

1.0 Submitter:

Name : Ratnam S.Vythilingam
Address : Best Putra Gloves Sdn Bhd, Jln Kg Mohd Taib, Kawasan Perindustrian Sg Choh, 48000, Rawang, Selangor Darul Ehsan. Malaysia
Phone No. : +03-60921042
Fax No. :+03-60912820

Date of Summary Prepared: 20 August 2010

2.0 Contact Person:

Name : Dr. Effendi Tenang
Phone No. : +03-60921042
Fax No. : +03-60912820

3.0 Name of the device:

Trade Name :1) BPG Latex Examination Gloves
2) Multiple or Customers' Trade Name
Device Name : Powdered, Natural Color, Latex Examination Gloves, Non-Sterile
Common Name : Examination Gloves
Classification Name : Patient Examination Gloves (Class 1)

4.0 Identification of the legally marketed device:

Class 1 patient examination gloves, powdered, that meets all the requirements of ASTM standard D 3578-01a^{e2} and FDA 1000 ml Water Leak Test.

5.0 Description of the Device:

The Powdered, Natural Color, Latex Examination Gloves, Non-Sterile meets all the requirements of ASTM standard D 3578-01a^{e2} and FDA 1000 ml Water Leak Test.

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6.0 Intended Use of the Device:

A powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

7.0 Summary of the technological characteristic of the devices:

The Powdered, Natural Color, Latex Examination Gloves, Non-Sterile are summarized with following technological characteristics compared to ASTM or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	D 3578-01a^{e2}	Meets
Physical Properties	D 3578-01a^{e2}	Meets
Freedom from Pinhole	D 3578-01a^{e2} FDA CFR 800.20	Meets
Powder Amount	D 3578-01a^{e2} D 6124 - 05	<10 mg/dm^2
Water Soluble Protein Content	D 3578-01a^{e2} D 5712-99	<200 µg/dm^2
Biocompatability	Primary Skin Irritation in Rabbits	Pass (No primary skin irritation)
	Dermal Sensitization	Pass (No 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 equivalent is the same as mentioned immediately above.

9.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data.

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

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10.0 Conclusion

It can be concluded that the Powdered , Natural Color, Latex Examination Gloves, Non-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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Effendi Tenang
Managing Director
Best Putra Gloves SDN BHD
Lot 1357-1358, JLN Kg. Mohd Taib
Kawasan Perindustrian Sg. Choh
48000 Rawang, Selangor Darul Ehsan, Malaysia

NOV 10 2010

Re: K101106
Trade/Device Name: Powdered, Latex Examination Gloves, Natural Color, Non-Sterile Model: MEP1
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: October 4, 2010
Received: October 21, 2010

Dear Dr. Tenang:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

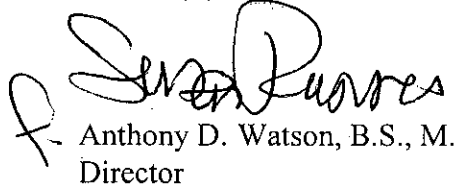
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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K101106

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INDICATIONS FOR USE

510(k) Number: K101106

Device Name: Powdered, Latex Examination Glove, Natural Color, Non-Sterile,
Model: MEP1

Indications For Use:

A powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Sincerely,

Dr. Effendi Tenang
(Managing Director)

Prescription Use_____
(Part 21 CFR 801 Subpart D)

OR

Over – The – Counter Use _XXX_____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elaine S. Maykall
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101106