JUL 0 5 2002

WRP Asia Pacific Sdn Bhd
147817V

K021119

510 (K) SUMMARY OF POWDERED BROWN LATEX SURGICAL GLOVES, STERILE

The device in this 510(k) submission is the Powdered Brown Latex Surgical Gloves, Sterile which is made of natural rubber latex. These gloves are intended to be worn by surgeons and/or operating room personnel to protect a surgical wound from contamination.

The Powdered Brown Latex Surgical Gloves, Sterile are substantially equivalent to Microptic, Brown Beaded Surgeon's Gloves (Powdered, Hypoallergenic) submitted and cleared under 510(k) number K960416. The only difference in this submission is to include the Expiration Date Labeling Claim and Protein Content Labeling Claim with no changes in product design. The results of stability study and protein content test conducted on Powdered Brown Latex Surgical Gloves, Sterile are submitted to support the expiration date labeling claim and protein content labeling claim.

Based on the results obtained through out the Stability Test, it can be concluded that the Powdered Brown Latex Surgical Gloves, Sterile produced by WRP Asia Pacific Sdn Bhd has demonstrated that the barrier properties, physical and mechanical properties, packaging integrity and sterility of the gloves are maintained for the duration of the claimed shelf-life (expiration date, i.e. 5 years). Also, based on the protein content test report, the protein level of the gloves is well below 50 μg/g and supports our protein content labeling claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. K. K Leong
Associate Manager, QA/RA
WRP Asia Pacific Sdn. Bhd.
Lot 1, Jalan 3, Kawasan Perusahaan
Bandar Baru Salak Tinggi,
43900 Sepang
Selangor Darul Ehsan,
MALAYSIA

JUL 5 - 2002

Re: K021119
Trade/Device Name: Powdered Brown Latex Surgical Gloves, Sterile with Expiration Date Labeling Claim and Protein Content Labeling Claim
Regulation Number: 878.4460
Regulation Name: Surgical Gloves
Regulatory Class: I
Product Code: KGO
Dated: April 4, 2002
Received: April 8, 2002

Dear Mr. Leong:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

Enclosure

WRP Asia Pacific Sdn Bhd

147817V

INDICATIONS FOR USE

Applicant: WRP Asia Pacific Sdn Bhd

510(k) Number (if known): K021119

Device Name: POWDERED BROWN LATEX SURGICAL GLOVES, STERILE WITH EXPIRATION DATE LABELING CLAIM AND PROTEIN CONTENT LABELING CLAIM

Indications For Use:

The surgical glove is a device made of natural rubber latex 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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021119

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

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43900 Sepang
Selangor Darul Ehsan
MALAYSIA

Re: K021119 (Powdered Brown Latex Surgical Gloves, Sterile with Expiration Date Labeling Claim)
K021159 (Powdered Latex Surgical Gloves, Sterile with Expiration Date Labeling Claim)

Dear Mr. Leong:

This letter notifies you that the data you submitted in your 510(k) submissions for the Powdered Brown latex Surgical Glove, Sterile with Expiration Date labeling Claim (K021119) and Powdered Latex Surgical Gloves, Sterile with expiration Date Labeling Claim (K021159) are inadequate to support a 5 year shelf life. Although FDA has determined that both 510(k)s are substantial equivalent, the shelf life labeling claim is a quality systems issue, not a premarket issue.

If you include a 5- year shelf life on your products with the data in the 510(k) submissions, FDA will consider your products misbranded.

If you wish to add a 5- year shelf life to the products labeling, please revise the test protocol you intend to use for the study, which should take FDA's July 5, 2002, comments into consideration. Please advise FDA of your intentions no later than July 31, 2002. If you have any questions, please contact Chiu Lin, Ph.D., Branch Chief, Infection Control Devices Branch at 301-443-8913.

Sincerely yours,

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