



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2001

Mr. Lin Weng Heng
Factory Manager
Koon Seng Sdn. Bhd
Batu 4 ½ Jalan Bakri
Muar, Johor
MALAYSIA

Re: K012714

Trade/Device Name: Royal Imperial Powder Free Polymer Coated Latex
Examination Glove with Protein Content Labeling Claim (50 Micrograms
or Less)

Regulation Number: 880.6250

Regulation Name: Patient Examination Gloves

Regulatory Class: I

Product Code: LYY

Dated: October 10, 2001

Received: October 15, 2001

Dear Mr.Heng:

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 Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 Indications for Use Statement : Include the following or equivalent for Use page. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the Indications for Use statement.

INDICATIONS FOR USE.

Applicant : Koon Seng Sdn. Bhd.

510 (k) Number (if known) : K012714 *

Device Name : Powder Free Polymer Coated Patient Examination Gloves

Indications For Use : Powder Free Polymer Coated Patient Examination Gloves are disposable device which is primarily intended for medical purpose worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Chin S. Lim
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012714

Prescription Use _____
Per 21 CFR S 01.109

OR

Over - The - counter _____

(Optional Format 1-2-96)

* For a new submission, do NOT fill in the 510(k) number blank.