THAI HUA HOLDING COMPANY LIMITED

K102840

FEB 18 2011

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
As required by §807.92(c)
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Powder-Free Polymer Coated Latex Examination Gloves
Protein Label Claim (50 micrograms or less of total water extractable protein per square decimeter of gloves)

1. Applicant
THAI HUA HOLDING CO., LTD.
238/1 Ratchadapisek 18, Huaykwang
Bangkok 10320 Thailand
Tel: 66-02-274 0471-7
Fax: 66-02-274 0231

2. Contact Person
Mr. Reyong Kittipol
Managing Director
Tel: 66-02-2740 471-7
Fax: 66-02-2740 231
Or
Kok-Kee Hon
Technical Advisor & Official Correspondent
6324 Meetinghouse Way
Alexandria, VA 22312 USA
Tel: 703-941-7656
Fax: 703-941-2551

3. Device Name: Patient Examination Gloves

4. Common Name: Powder-Free Polymer Coated Latex Examination Gloves with Protein Labeling (50microgram or less of total water extractable proteins per square decimeter of gloves)

5. Classification: Class I

6. Predicate Device: This glove is substantially equivalent to legally market Latex Patient Examination Gloves, class I (21CFR 880.6250), product code LYY that meet all the requirements of ASTM D 3578-05 Standard Specification for Rubber Examination Gloves.

7. Device Description: Powder-Free Polymer Coated Latex Examination Gloves with Protein Labeling (50microgram or less of total water extractable proteins per square decimeter of gloves), non-sterile.

8. Intended Use of the Device:
This glove is disposable and intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

9. Technological Characteristics of Device:
The Powder Free-Polymer Coated Latex Examination Gloves characteristics are summarized below as compared to ASTM requirements and to predicate devices:

Characteristic	Standard
Dimensions	Meets ASTM D 3578-05
Physical Properties	Meets ASTM D 3578-05
Freedom From Holes	Meets ASTM D 3578-05, AQL 1.5 Meets ASTM D 5151-06
Protein Content	Meets ASTM D 5712-99, Less than 50µg/dm^2
Powder Free Residue	Meets ASTM D 6124-06, Less than 2 mg per glove
Biocompatibility	Passes Primary Skin Irritation in Rabbits Test as described in Consumer Product Safety Commissions Title 16, Chapter II, Part 1500.41& 1500:3(c)(4) Passes Guinea Pig Sensitization Test as per ISO 10993-10: 2002(E), Dermal Sensitizations Assay- Closed Patch Test

10. Performance Data: Are summarized above

11. Clinical Data: Not required

12. Conclusion: Powder-Free Polymer Coated Latex Examination Gloves with Protein Labeling (50microgram or less of total water extractable proteins per square decimeter of gloves) base on the nonclinical tests performed, this glove is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate device identified or legally marketed Latex Patient Examination Gloves, Class I (21CFR 880.6250), product code LYY.

13. Prepared Date: December 4th, 2010

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

Mr. Kok-Kee Hon
Official Correspondent
Thai Hua Holding Company, Limited
6324 Meetinghouse way
Alexandria, Virginia 22312-1718

FEB 18 2011

Re: K102840
Trade/Device Name: Provide-Free Polymer Coated Latex Examination Gloves with Protein Labeling (50microgram or Less of Total Water Extractable Proteins Per Square Decimeter of Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: December 22, 2010
Received: December 28, 2010

Dear Mr. Hon:

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.

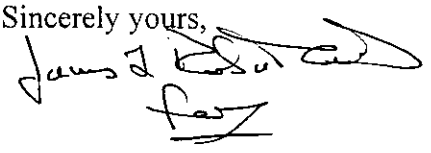
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

INDICATION FOR USE

Applicant: THAI HUA HOLDING CO., LTD

510 (K) Number: .....

Device Name: Powder-Free Polymer Coated Latex Examination Gloves with Protein Labeling (50microgram or less of total water extractable proteins per square decimeter of gloves)

Indications for Use:

This glove is disposable and intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

Prescription Use_____ AND/OR Over the-Counter Use X

(Part 21CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth B. Claverie - Wells

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

510(k) Number: K102840