# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

**As required by §807.92(c)**

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

**Powder Free Nitrile Examination Gloves (Blue)**

**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 Nitrile Examination Gloves (Blue) (CFR 880.6250)

**5. Classification:** Class I

**6. Predicate Device:** The Powder Free Nitrile Examination Gloves is substantially equivalent to legally market K051333 Nitrile Patient Examination Gloves, class I (21CFR 880.6250), product code LZA that meet all the requirements of ASTM D 6319-05 Standard Specification for Nitrile Examination Gloves for Medical Application.

**7. Device Description:** Powder Free Nitrile Examination Gloves (Blue), 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 Nitrile Examination Gloves characteristics are summarized below as compared to ASTM requirements and to predicate devices:

| CHARACTERICS | STANDARDS | DEVICE PERFORMANCE |
|---|---|---|
| Dimensions | ASTM D 6319-00a(2005) | Meets |
| Physical Properties | ASTM D 6319-00a(2005) | Meets |
| Freedom from Holes | ASTM D 6319-00a(2005)<br>ASTM D 5151-06 | Meets<br>Meets AQL 1.5 |
| Powder Free Residual | ASTM 6124-06 | Less than 2 mg per glove |
| Biocompatibility Primary Skin Irritation Test in Rabbits | Consumer Product Safety Commission, Title 16, Chapter II, Part 1500.41& 1500:3(C)(4) | Passes |
| Biocompatibility Guinea Pig Sensitization Test | ISO 10993-10: 2002(E), Dermal Sensitiztion Assay-Closed Patch Test | Passes |

**10. Performance Data** Are summarized above

**11. Clinical Data:** Not required

**12. Conclusion:** The Powder Free Nitrile Examination Gloves (Blue) base on the nonclinical tests performed, the Powder-Free Nitrile Examination Gloves is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate device identified or legally marketed Nitrile Patient Examination Gloves, Class I (21CFR 880.6250), product code LZA.

**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

MAR 17 2011

Re: K102846
Trade/Device Name: Powder-Free Nitrile Examination Gloves (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: February 7, 2011
Received: February 11, 2011

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.

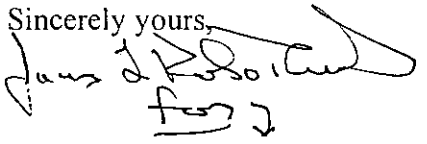
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

**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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth T. Claverie-Wilson

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

510(k) Number: K102846