



Food and Drug Administration
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August 12, 2014

Hebei HongSen Plastics Technology Company, Limited
C/O Mr. Charles Shen
Official Correspondent
Manton Business and Technology Services
5 Carey Street
Pennington, New Jersey 08534

Re: K140988

Trade/Device Name: Powder Free Sterile Latex Surgical Gloves, Yellow Color
(Brand Name: Titanfine)

Regulation Number: 21 CFR 878.4460

Regulation Name: Surgeon's Glove

Regulatory Class: I

Product Code: KGO

Dated: July 11, 2014

Received: July 15, 2014

Dear Mr. Shen:

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 contact 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>. 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K140988

Device Name

Powder Free Sterile Latex Surgical Gloves, Yellow Color (Brand Name: Titanfine)

Indications for Use (Describe)

The powder free sterile latex surgical glove, yellow color (Brand Name: Titanfine), is a disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

5.1 Submitter & Foreign Manufacture Identification

Hebei HongSen Plastics Technology Co., Ltd
The Eastern Industrial Accumulation Area
Nangong Town, Xingtai City, Hebei Province, China
Tel: 86- 311-85656588
Submitter's FDA Registration Number: 3010582952

5.2 US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
5 Carey Street
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

5.3 Date of Summary: March 15, 2014

5.4 Device Name:

Proprietary Name:	Powder Free Sterile Latex Surgical Gloves, Yellow Color (Brand Name: Titanfine)
Common Name:	Surgeon's glove
Classification Name:	Surgeon's glove
Device Classification:	I
Regulation Number:	21 CFR 878.4460
Panel: General	General & Plastic Surgery
Product Code:	KGO

5.5 Predicate Device Information:

(1) K121897, "Protexis' Latex Basic, Sterile Latex Powder-Free Surgical Glove with Protein Content Label Claim of 50µg/dm² or less (Cream)", manufactured by "Cardinal Health"

5.6 Device description:

Powder Free Sterile Latex Surgical Gloves, Yellow Color (Brand Name: Titanfine) are made of natural rubber, and are sterile that meets all of the requirements of ASTM standard D 3577-2009. They have yellow color.

5.7 Intended Use:

The powder free sterile latex surgical glove, yellow color (Brand Name: Titanfine) is a disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

5.8 Comparison to Predicate Devices

The powder free sterile latex surgical gloves, yellow, are compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

K121897, “Protexis' Latex Basic, Sterile Latex Powder-Free Surgical Glove with Protein Content Label Claim of 50µg/dm² or less (Cream)”, manufactured by “Cardinal Health”

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device (K121897)
Indication for Use	The powder free sterile latex surgical glove, yellow color (Brand Name: Titanfine) is a disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	A powder-free sterile surgeon's glove is a disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.
Basic Design	A garment covering the hand and waist area. Gloves have separate sheaths or openings for each finger and the thumb.	Same
Materials	Natural rubber	Same
Size	6, 6.5, 7, 7.5, 8, 8.5, 9	Information not available
Single Use	Yes	Yes
Color	Yellow	Cream
Sterile	Sterile (Irradiation)	Sterile

Our device is essentially identical to the predicate device in terms of indications for use, design, and material between our device and the predicate devices. The only minor difference is that the predicate device has cream color, while our device in submission has yellow color.

The following table shows similarities and differences of the performance between our device and the predicate devices. One minor difference is that predicate device has an extractable protein limit of 50 µg/dm², where our device has a limit of 200 µg/dm². This minor difference does not impact the safety of the device as 200 µg/dm² is still a well accepted safe limit.

Tests were conducted following the recommended procedures outlined in the respective consensus standards, and results for Powder Free Sterile Latex Surgical Gloves, Yellow Color (Brand Name: Titanfine), manufactured by “*Hebei HongSen Plastics Technology Co., Ltd.*” met all relevant requirements in the test standards, and are comparable to the predicate device.

Table 5.2: Comparison of Physical, Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K121897)
Dimension	Meets ASTM D 3577-09 (Published 02/1/2009)	Meets ASTM D 3577 (Publication date unknown)
Physical Property	Meets ASTM D 3577-09 (Published 02/1/2009)	Meets ASTM D 3577 (Publication date unknown)
Free of Pinhole	Meets ASTM D5151 (AQL 1.5) (Published 08/20/2012)	Meets ASTM D5151 (Publication date unknown)
Residue Powder	Meets ASTM D6124 (Published 08/20/2012)	Meets ASTM D6124 (Publication date unknown)
Water Soluble Protein	Meets ASTM D5712-10 (Published 02/01/2009)	Meets ASTM D5712 (Publication date unknown)
Primary Skin Irritation (ISO 10993-10: 2010)	Not a primary skin irritant under the conditions of the study	Same
Dermal sensitization (ISO 10993-10: 2010)	Not a dermal sensitizer under the conditions of the study	Same

5.9 A brief discussion of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Subject Device is safe and effective, and whose performance meets the requirements of its user-defined acceptance criteria and intended uses:

Powder Free Sterile Latex Surgical Gloves, Yellow Color (Brand Name: Titanfine) meet requirements per ASTM D3577-09, ASTM D6124-06, ASTM D 5151-06, ASTM D5712-10 and ISO 10993-10. It is safe and effective, and its performance meets the requirements of its pre-defined acceptance criteria and intended uses.

5.10 A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

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

5.11 Substantial Equivalent Conclusions

Based on the comparison of intended use, design, materials, and performance, our Powder Free Sterile Latex Surgical Gloves, Yellow Color (Brand Name: Titanfine) are substantial equivalent to its predicate devices.