



Food and Drug Administration
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December 22, 2014

Hebei Hongsen Plastics Technology Co., Ltd.
C/O Mr. Charles Shen
Manager
Manton Business and Technology Services
853 Dorchester LN, Unit-B
New Milford, NJ 07646

Re: K140989

Trade/Device Name: Powder Free Sterile Nitrile Surgical Gloves; White Color
(Brand Name: Titanfine)

Regulation Number: 21 CFR 878.4460

Regulation Name: Surgeon's Glove

Regulatory Class: I

Product Code: KGO

Dated: November 23, 2014

Received: November 26, 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Enclosure

Indications for Use

510(k) Number (if known)
K140989

Device Name
Powder Free Nitrile Surgical Gloves, White Color (Brand Name: Titanfine)

Indications for Use (Describe)

The powder free nitrile surgical glove, white color (Brand Name: Titanfine), is a sterile and single use device made of synthetic rubber intended to be worn by operation room personnel to protect a surgical wound from contamination. The gloves do not contain lubricating or dusting powder.

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.

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Section 5: 510(k) Summary: K140989

This summary of 510k is being submitted in accordance with the requirements of 21CFR 807.92

5.1 Submission Sponsor

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5.2 Submission Correspondent

Manton Business and Technology Services
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5.3 Date of Summary: December 16, 2014

5.4 Device Name:

Proprietary Name:	Powder Free Nitrile Surgical Gloves, White 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) K122557, "Motex Powder Free Nitrile Surgical Gloves, White and Green Color", manufactured by "Shanghai Motex Healthcare Co., Ltd."

5.6 Device description:

Surgical glove is a disposable device worn on the surgical room personnel's hand or finger to prevent contamination during surgical procedures. The principle of operation is to provide a physical barrier between the surgical personnel's hands and the patient's open wound.

The powder free nitrile surgical gloves described in this submission are made of synthetic nitrile rubber, and are sterile that meets all of the requirements of ASTM standard D 3577-2009. They have white color and are single use.

The powder free nitrile surgical gloves described in this submission are tested for dimension, percent elongation, tensile, tensile at 500% elongation, free of pinholes, residue powder, water soluble proteins. The test results conform to related requirements in ASTM 3577-2009.

The powder free nitrile surgical gloves described in this submission are also tested biocompatibility per ISO 10993-10. The test results conform to related requirements in the standard.

The product sterilization is performed using radiation and the procedure is validated per ISO 11137-2: 2006.

5.7 Indications for Use:

The powder free nitrile surgical glove, white color (Brand Name: Titanfine), is a sterile and single use device made of synthetic rubber intended to be worn by operation room personnel to protect a surgical wound from contamination. The gloves do not contain lubricating or dusting powder.

5.8 Comparison to Predicate Devices

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

(1) K122557, "Motex Powder Free Patient Nitrile Surgical Gloves", manufactured by "Shanghai Motex Healthcare Co., Ltd."

Substantial equivalence is established with respect to intended use, Labeling, performance, design, materials, and other applicable characteristics. Side-by-side comparison tables that include the following four areas are provided below:

- A: Indication for Use, design and materials
- B: Labeling (labels, instructions for use, promotional material) for the legally marketed device to which substantial equivalence is claimed.

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C: Performance data supporting substantial equivalence

A: Indications for Use, Design, and Material:

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

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

Description	Subject Device (K140989)	Predicate Device (K122557)
Indication for Use	The powder free nitrile surgical glove (Brand Name: Titanfine) is a sterile and single use device made of synthetic rubber intended to be worn by operation room personnel to protect a surgical wound from contamination. The gloves do not contain lubricating or dusting powder.	A Surgeon's Glove is a sterile and single use device made of synthetic rubber intended to be worn by operation room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.
Basic Design	A device covering the hand and wrist area. Gloves have separate sheaths or openings for each finger and the thumb.	Same
Materials	Nitrile rubber	Same
Size	6, 6.5, 7, 7.5, 8, 8.5, 9	6, 6.5, 7, 7.5, 8, 8.5
Single Use	Yes	Yes
Color	White	White and green
Sterile	Sterile (Irradiation)	Sterile (Irradiation)

The subject device is essentially identical to the predicate device in terms of indications for use, design, and material between subject device and the predicate devices. The only minor difference is that the predicate device has both green and white color, while subject device in submission has only white color. This minor difference in color does not impact the efficacy and safety of the gloves, demonstrated by satisfactory performance and biocompatibility test results, and the fact that the white pigment of TiO₂ has a well established safety profile.

B: Labeling:

The following table shows similarities and differences of key elements of the labeling between subject device and the predicate devices.

Table 5.2: Comparison of Key Elements in Labeling

Description	Subject Device (K140989)	Predicate Device (K122557)
Product Name	Yes	Yes
Indication for Use	Yes	No
Technical Characteristics (Powder, Nitrile, etc)	Yes	Yes
Manufacturer Name and Address	Yes	Yes
Product Model, Size, and Lot Number	Yes	Yes
Single Use Statement	Yes	Yes
Sterility Statement	Yes	Yes
Expiration Date	No	Yes
Information on Wrapper	Size, and Left/Right	Size

The label for this subject device is identical to K122557, except for two minor differences. The first one is that the label for subject device has Indications for Use on it, while the second one being that the predicate device claims expiration date, while the subject device does not.

C: Performance and Specifications

The following table shows similarities and differences of the specification/performance between subject device and the predicate devices. Tests were conducted following the recommended procedures outlined in the respective consensus standards, and results for Powder Free Nitrile Surgical Gloves, White Color (Brand Name: Titanfine) met all relevant requirements in the specifications and test standards. The subject device/gloves are equivalent with the predicate device in terms of performance and technological characteristics.

Table 5.3: Comparison of Specifications and Performance with Predicate Device

Description	Subject Device (K140989)	Predicate Device (K122557)
Dimension	Length: ≥ 265 mm Width: within ± 6 mm of the specified value in ASTM 3577: 2009 Palm, Finger, Cuff Thickness: ≥ 0.10 mm	Length: ≥ 265 mm Width: within ± 6 mm of the specified value in ASTM 3577: 2009 Palm, Finger, Cuff Thickness: ≥ 0.10 mm
Tensile Strength (MPa)	≥ 17	≥ 17

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Tensile at 500 % Elongation (MPa)	≤ 7.0	≤ 7.0
Percent Elongation	≥650	≥650
Free of Pinhole	Free of pinholes at AQL = 1.5	Free of pinholes at AQL = 1.5
Residue Powder	≤ 2.0 mg	≤ 2.0 mg
Water Soluble Protein	≤ 200 µg/dm ²	≤ 200 µg/dm ²
Primary Skin Irritation (ISO 10993-10: 2010)	Not a primary skin irritant (Grade <1.0) under the conditions of study	Not a primary skin irritant
Dermal sensitization (ISO 10993-10: 2010)	Not a dermal sensitizer (Grade 0 or 1) under the conditions of study	Not a dermal sensitizer

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 Nitrile Surgical Gloves, White Color (Brand Name: Titanfine) meet requirements per ASTM D3577-09, ASTM D6124-06, ASTM D 5151-06, ASTM D5712-10 and ISO 10993-10. 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 cleared by the 510(k) process.

5.11 Substantial Equivalent Conclusions

Based on the comparison of intended use, design, materials, and performance, the subject device is as safe and effective and substantially equivalent to the predicate device.