MAR 1 1 2011

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

Submitter & Foreign Manufacture Identification

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Submitter's FDA Registration Number: N/A

US Agent and Contact Person

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Date of Summary: June 22, 2010

Name of Device: Surgical Gown
Classification Name: Gown, Surgical
Product Code: FYA
Regulation Number: 807.4040

Predicate Device Information:

(1) K052550, "International Medsurp Connection Surgical Gowns (IMC Gowns)", manufactured by "International Medsurp Connection Surgical Gown Inc" located in Schaumburg, Illinois.
(2) K070431, Welmed Surgical Gowns, manufactured by Welmed, Inc. located in Grayslake, Illinois.

Device description:

The Jincheng Surgical Gowns are an open back gown manufactured from nonwoven fabric that the fibres are mechanically bonded together. They are full length, constructed with raglan sleeves, hook and loop neck closures, and tie waist closures. They come with three different types of materials (SMS polypropylene fabric, Spunlace fabric, and SFT fabric) and four different design styles (regular, reinforced, regular with guider, and

reinforced with guider). Therefore there are total eight different models involved in this submission. They are:

Jincheng SMS Gowns

- SMS Reinforced Gown
- SMS Reinforced Gown with Guider

Jincheng Spunlace Gowns

- Spunlace Regular Gown
- Spunlace Regular Gown with Guider
- Spunlace Reinforced Gown
- Spunlace Reinforced Gown with Guider

Jincheng SFT Gowns

- SFT Gown
- SFT Gown with Guider

Each design has four different sizes: Medium (M), Large (L), Extra Large (XL), and Extra Extra Large (XXL).

All gowns come with sterile and non-sterile. Non-sterile surgical gowns are to be sold to OEMs for EtO sterilization according to ISO 11135. Sterile Surgical Gowns are to be sold directly to users after EtO sterilization validation to ISO 11135.

Intended Use:
The Jincheng Surgical Gown is a single use, sterile or none sterile (sterile before use) item that is intended to be used in operation room as a protective covering, for operating room staff, from the transferring of body fluids and particulates.

Gowns provided as sterile and non-sterile.

Non-sterile surgical gowns are to be sold to OEMs for EtO sterilization according to ISO 11135. Sterile Surgical Gowns are to be sold directly to users after EtO sterilization validation to ISO 11135.

Comparison to Predicate Devices
Hangzhou Jincheng Surgical Gowns are compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K052550, "International Medsurp Connection Surgical Gowns (IMC Gowns)", manufactured by "International Medsurp Connection Surgical Gown Inc" located in Schaumburg, Illinois.
(2) K070431, Welmed Surgical Gowns, manufactured by Welmed, Inc. located in Grayslake, Illinois.

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 1 (K070431)	Predicate Device 2 (K052550)
Indication for Use	Are used as protective covering for operating room staff, from the transferring of body fluids and particulates.	Same	Same
Basic Design	Full length, constructed with raglan sleeves, neck closures, and waist closures.	Same	Same
Additional Features	Regular and reinforced	Information not available	Regular and reinforced
Materials/size	Non-woven (SMS, Spunlace, SFT)/various size	Non-woven (SMS, SPP)/various size	Non-woven (various material)/various size
Single Use	Yes	Yes	Information not available
Sterile	Both sterile and non sterile	Both sterile and non sterile	Information not available

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Section 5: 510k Summary

The following table shows similarities and differences of the performance between our device and the predicate devices. Tests were conducted following the recommended procedures outlined in the respective consensus standards, and results for Jincheng Surgical Gowns met all relevant requirements in the test standards, and are comparable to the predicate device.

Details of the test procedures and results can be found in Sections 15 (Biocompatibility) and 18 (Performance Testing-Bench).

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device 1 (K070431)	Predicate Device 2 (K052550)
Cytotoxicity	No Toxic Effect (ISO10993-5)	No Toxic Effect (ISO10993-5)	No Toxic Effect (ISO10993-5)
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	No Effect (ISO 10993-10)	No Effect (ISO 10993-10)
Hydrostatic Pressure: Water Resistance	AATCC Test Method 127: 1998: Water Resistance: Hydrostatic Pressure Test	Same	Same
Impact Penetration Test : Water Resistance	AATCC 42: 2007: Water Resistance: Impact Penetration Test	Same	Same
Breaking Strength	ASTM D5034: 2008: Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Same	Same
Elmedorf Tear	In house method similar to ASTM - D5734-95:2001	ASTM - D5734-95:2001 Standard Test Method for Tearing Strength of Nonwoven Fabrics by Falling-Pendulum (Elmendorf) Apparatus	N/A
Flammability	16 CFR 1610: Flammability Test Method (CPSC CS-191-53) Standard for Flammability of Clothing Textiles	Same	Same
Lint	ISO 9073-10: Lint and Other Particles Generation in the Dry State	Same	IST 160.1

More details of non-clinical tests are summarized in *Section 15 and Section 18.*

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:

Jincheng Surgical Gown meet requirements per AATCC Test Method 127: 1998, AATCC 42: 2007, ASTM D5034, 16 CFR 1610, ISO 9073-10, ISO 10993-5, and ISO 10993-10. It is safe and effective, and it's performance meets the requirements of its pre-defined acceptance criteria and intended uses.

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.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Jincheng Surgical Gowns are substantial equivalent to its predicate devices.

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

Hangzhou Jincheng Medical Supplier Manufacture Company, Limited
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Manton Business and Technology Services
5 Carey Street
Pennington, New Jersey 08534

MAR 1 1 2011

Re: K102692
Trade/Device Name: Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: February 17, 2011
Received: February 18, 2011

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 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

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The gowns involved in this submission are summarized in the Table below:

Material	Design	Sterilization	Model Name	Sizes
SMS	Reinforced	Sterile	SG74100	M, L, XL, XXL
		Non-sterile	SG74700	M, L, XL, XXL
	Reinforced with Guider	Sterile	SG78100	M, L, XL, XXL
		Non-sterile	SG78700	M, L, XL, XXL
Spunlace	Regular	Sterile	SG80100	M, L, XL, XXL
		Non-sterile	SG80700	M, L, XL, XXL
	Regular with Guider	Sterile	SG82100	M, L, XL, XXL
		Non-sterile	SG82700	M, L, XL, XXL
	Reinforced	Sterile	SG84100	M, L, XL, XXL
		Non-sterile	SG84700	M, L, XL, XXL
	Reinforced with Guider	Sterile	SG88100	M, L, XL, XXL
		Non-sterile	SG88700	M, L, XL, XXL
SFT	Gown	Sterile	SG94100	M, L, XL, XXL
		Non-sterile	SG94700	M, L, XL, XXL
	Gown with Guider	Sterile	SG98100	M, L, XL, XXL
		Non-sterile	SG98700	M, L, XL, XXL

Gowns provided as sterile and non-sterile.

Non-sterile surgical gowns are to be sold to OEMs for EtO sterilization according to ISO 11135. Sterile Surgical Gowns are to be sold directly to users after EtO sterilization validation to ISO 11135.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth T. Claunier Welsh

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

510(k) Number: K102692