K123787

JUL 17 2013

Section 2: 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

Jingzhou Haixin Green Cross Medical Products Co., Ltd
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Contact person: Bill Liao
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Submitter's FDA Registration Number: N/A

1. **US Agent and Contact Person**

Xiangyang Song
6 Vanderblet Road,
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Date of Summary: December 03, 2012, Date of Revision 1: December 26, 2012, Date of Revision 2: May 17, 2013

2. **Regulatory Information**

Name of Device: GreenCross Surgical Mask
Model No.: GFM12
Type: Tie-on, Earloop
Common Name: Surgical Mask
Panel: General & Plastic Surgery
Device Classification: Class II
Regulation Number: 878.4040
Product Code: FXX
Classification Name: Mask, Surgical

3. **Predicate Device Information:**
K101000: Surgical Mask (For Single Use Only) by Wellmien (Suzhou) Imp. & Exp. Trading Co., Ltd

4. **Device description:**

GreenCross surgical masks, Type: Earloop or Tie-on, are pleated 3-ply mask. Inner and outer layers are made of 100% spun-bond polypropylene. Middle player is made of 100% meltblown polypropylene filter media. Ear-loops are made of soft latex free elastic loops. All of the materials used in the construction of the GreenCross surgical masks are being used in currently marketed devices, except the nose piece used plastic wire instead of aluminum wire. (see predicate information)

5. Intended Use:

The GreenCross Surgical Masks (for single use only) are indicated as a protective nose and mouth covering for health care workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situations where there is a risk of microorganism, body fluid, and particulate aerosol transfer.

6. Comparison to Predicate Devices

GreenCross Surgical Mask is compared with its Predicate devices: K101000: Surgical Mask (For Single Use Only) by Wellmien (Suzhou) Imp. & Exp. Trading Co., Ltd. The design, material, and other technical characteristics of these two devices are very similar, except that the nose piece for GreeCross Surgical Mask used plastic wire instead of aluminum wire, also the size, color & design type (Ear Loop or Tie-on) are different to predicate device. These features are not expected to affect the safety and performance of the device.

Comparison of Intended Use, Design, Material and Specifications

Description	Our Device	Predicate Device (K101000)
Indication for Use	Nose and mouth covering for health care workers and patients to prevent microorganism, body fluid, and particulate aerosol transfer.	Same
Layers	Three	Three
Materials	Outer layer is made of 100% spun-bond polypropylene. Middle player is made of 100% meltblown polypropylene filter media. Inner layer is made of 100% spun-bond polypropylene. Ear-loops are made of soft latex free elastic loops. The nose piece is plastic wire	Outer layer is made of 100% spun-bond polypropylene. Middle player is made of 100% meltblown polypropylene filter media. Inner layer is made of 100% spun-bond polypropylene. Ear-loops are made of soft elastic loops. The nose piece is malleable aluminum wire

Dimensions	175±5 mm x90±5 mm	Large: 180x90mm, Medium: 175 x95mm, Small: 145x90 mm
Mask style	Flat Pleated	Flat Pleated
Design	EarLoop, Tie-on	EarLoop
Anti Fog Shield	N/A	N/A
Color	white	Blue
NIOSH certification	N/A	N/A

Comparison of Device Performance

Test	Our Device	Predicate Device (K101000)
Fluid Resistance Performance ASTM F1862	29 out of 32 pass at 120 mm Hg	31 out of 32 pass
Particle Filtration Efficiency ASTM F2299	99.1%	99.8%
Bacteria Filtration Efficiency ASTM F2101	99.8%	99.9%
Differential Pressure (Delta-P) MIL-M-36945C	2.6-2.9 (mm Water/cm^2)	3.7-4.0 (mm Water/cm^2)
Flammability 16CFR 1610	Class 1 None Flammable	Class 1 None Flammable
Biocompatibility ISO 10993-5, -10	Biocompatible	Biocompatible

7. Discussion of Non-Clinical Tests Performed to Determine Substantial Equivalence

The following non-clinical tests were performed to determine substantial equivalence. Tests were conducted following the recommended procedures outlined in the following standards. Test results met all relevant requirements in the test standards, and are comparable to the predicate device.

(1) ASTM F2101 Bacterial Filtration Efficiency（BFE）
(2) Pressure Differential（Delta P）MIL-M-36945C Cl. MIL-M-36945C 4.4.1.1.1
(3) ASTM F2299 Latex Particle Challenge（PFE）
(4) 16 CFR Part 1610 Flammability
(5) Biocompatibility per ISO 10993

(6) ASTM F1862 Fluid Resistant – Synthetic Blood Penetration Resistant Test

It is our conclusion that performance testing met all relevant requirements of the above said test standards. More detail comparison of the design, technical, and performance characteristics to the predicted device are summarized in "**510(k) Premarket Notification for Jingzhou Haixin Surgical Mask**" chapter 4 summary report, section 4.1 to 4.4. More details of non-clinical tests are summarized in Chapter 4, section 4.5 and 4.6

8. Discussion of Clinical Tests Performed

Not applicable

9. Conclusions

The GreenCross surgical mask has the same intended use and technological characteristics as the predicate devices. Moreover, bench testing contained in this submission demonstrates that the technological characteristics of GreenCross Surgical masks do not raise any new questions of safety or effectiveness. Therefore, GreenCross surgical masks By Jingzhou Haixin Green Cross Medical Products Co., Ltd are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 17, 2013

Jingzhou Haixin Green Cross Medical Products Company, Limited
C/O Mr. Xiangyang Song
6 Vanderbelt Road
ACTON MA 01720

Re: K123787
Trade/Device Name: GreenCross Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: May 16, 2013
Received: June 14, 2013

Dear Mr. Song:

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

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123787

Section 1: Indication for Use Statement

Device name: GreenCross Surgical Mask

The GreenCross Surgical Masks are indicated as a protective nose and mouth covering for health care workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situations where there is a risk of microorganism, body fluid, and particulate aerosol transfer.

Prescription Use _____ Over the Counter Use __X__

Elizabeth F. Claverie
2013.07.16 18:50:22 -04'00'

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

510(k) Number: K123787