K101000

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

1. **Contact Information**

AUG - 5 2010

Submitter & Foreign Manufacturer Identification
Wellmien (Suzhou) Imp. & Exp. Trading Co., Ltd
1-711, No.636 Ganjiang East Road
Suzhou, Jiangsu Province, China, Zip code: 215005
Tel: 86-512-81881706

Submitter's FDA Registration Number: N/A

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

Date of Summary: March 23, 2010 **Date of Revision 1**: June 5, 2010

2. **Regulatory Information**

Name of Device: Surgical Mask (For Single Use Only)
Panel: General Hospital
Class: Class 2
Regulation Number: 21 CFR 807.4040
Product Code: FXX
Classification Name: Mask, Surgical

3. **Predicate Device Information:**
K060776: Surgical Face Mask (Yellow, White, Green, Pink) by Hong Ya Non-Woven Products Co., Ltd

4. **Device description:**
WELLMIEN's surgical masks (for single use only) 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 elastic loops。The nose piece for all WELLMIEN's face masks is malleable aluminum wire. All of the materials used in the construction of the WELLMIEN's surgical masks are being used in currently marketed devices. (see Predicate Device information)

5. **Intended Use:**
The Wellmien 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**

WELLMIEN Surgical Mask (for single use only) is compared with it Predicate Device: K060776: Surgical Face Mask (Yellow, White, Green, Pink) by Hong Ya Non-Woven Products Co., Ltd. The design, material, and performance of both devices are very similar, and the two products are substantially equivalent in safety and effectiveness.

Comparison of Intended Use, Design, Material, and Specifications

Description	**Our Device**	**Predicate Device (K060776)**
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.	Outer layer is made of 100% spun-bond polypropylene.
	Middle player is made of 100% meltblown polypropylene filter media.	Middle player is made of 100% meltblown polypropylene filter media.
	Inner layer is made of 100% spun-bond polypropylene.	Inner layer is made of 100% spun-bond polypropylene.
	Ear-loops are made of soft elastic loops.	Ear-loops are made of soft elastic loops.
	The nose piece is malleable aluminum wire	The nose piece is malleable aluminum wire
Dimensions	Large: 18x9cm, Medium: 17.5x9.5cm, Small: 14.5x9 cm	N/A
Mask style	Flat Pleated	Flat Pleated
Design	Ear Loop	Ear Loop
Color	Blue	Yellow, White, Green, Pink
NIOSH certification	N/A	N/A

Comparison of Device Performance

Test	Our Device	Predicate Device (K060776)
Fluid Resistance Performance	Fluid Resistance	Fluid Resistance
Particle Filtration Efficiency	99.8%	96.8%
Bacteria Filtration Efficiency	99.9%	At least 99.9%
Differential Pressure (Delta-P)	3.7-4.0 (mm Water/cm^2)	Average 2.34 (mm Water/cm^2)
Flammability	Class 1 None Flammable	Class 1 None Flammable
Biocompatibility	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 respective consensus standards. Test results met all relevant requirements in the test standards, and are comparable to the predicate device.

(1) Bacterial Filtration Efficiency（BFE）: ASTM F2101-07
(2) Pressure Differential（Delta P）
(3) Latex Particle Challenge（PFE）: ASTM F2299-03
(4) Flammability: 16 CFR 1610
(5) Biocompatibility per ISO 10933
(6) Fluid Resistant – Synthetic Blood Penetration Resistant Test: ASTM F1682-07

More detailed comparison of the design, technical, and performance characteristics to the predicate device are summarized in ***Section 7: Summary Report.*** More details of non-clinical tests are summarized in ***Section 7.5 and 7.6.***

8. Discussion of Clinical Tests Performed
Not applicable

9. Conclusions

The WELLMIEN's surgical masks (for single use only) have the same intended use and technological characteristics as the predicate devices.

Moreover, bench testing contained in this submission demonstrates that the technological characteristics do not raise any new questions of safety or effectiveness。 WELLMIEN's surgical masks (for single use only) 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Wellmien (Suzhou) Import and Export Company, Limited
C/O Mr. Chengyu Shen
Manton Business and Technology Services
5 Carey Street
Pennington, New Jersey 08534

AUG - 9 2010

Re: K101000
Trade/Device Name: Wellmien Surgical Mask (for single use only)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: June 2, 2010
Received: June 25, 2010

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.

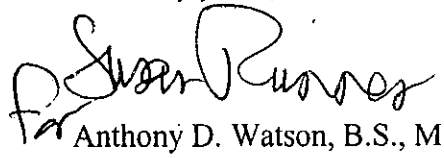
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

K101000

Indications for Use

510(k) Number (if known): K101000

AUG - 9 2010

Device Name: Wellmien Surgical Mask (for single use only)

Indications for Use:

The Wellmien 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.

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 Claverie Williams

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

510(k) Number: K101000