510(k) Summary

The assigned 510(k): K121925

1. Submitter
Name: Suzhou Colour-way Enterprise Development Co., Ltd
Address: 83 Changping Road, Dongqiao Industrial Area, 215152, Suzhou, Jiangsu, China
TEL: 86-512-65371793
FAX: 86-512-65379978
Date summary prepared: June 14, 2013

2. Contact person
Name: Miss Zhu Yingqiu
TEL: 86-512-65371793
FAX: 86-512-65379978
E-mail: zhuyingqiu@hotmail.com

3. Device Identification
Trade name: Powdered Latex Surgeon’s Glove
Common name: Surgeon’s glove
Classification name: Surgeon’s glove
Classification number: KGO, class I
Regulation number: 21CFR 878.4460

4. Identification of the Predicate device
Trade name: Powdered Latex Surgeon’s Glove
510(k) number: K062797
Product code: KGO

5. Description of the Device
The glove is made of natural rubber latex. It is powdered with absorbable dusting powder. The sterility status is sterile. It meets all the requirements of ASTM D3577-09™. No colorant is added during manufacture of our Powdered Latex Surgeon’s Glove. The color of our glove is ivory.

6. Directions for use:
The product is made of natural rubber latex which may cause allergic reactions. It is powdered with absorbable dusting powder. The Powdered Latex Surgeon’s Glove is sterilized by radiation. It is single use only, and can not be reused. Don’t use if the package is damaged.
7. Indications for Use:
This Powdered Latex 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.

8. Summary of the technological characteristics of the device compared to the predicate device

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>New Device Colour-way’s Glove</th>
<th>Predicate Device Powdered Latex Surgeon’s Glove (K062797)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Composition</td>
<td>Natural Rubber Latex</td>
<td>Natural Rubber Latex</td>
</tr>
<tr>
<td>Colorant</td>
<td>No colorant</td>
<td>No colorant</td>
</tr>
<tr>
<td>Design</td>
<td>Single use</td>
<td>Single use</td>
</tr>
<tr>
<td></td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
<tr>
<td></td>
<td>Powdered</td>
<td>Powdered</td>
</tr>
<tr>
<td></td>
<td>Beaded Cuff</td>
<td>Beaded Cuff</td>
</tr>
</tbody>
</table>

Indications for Use:
This Powdered Latex Surgeon’s Glove is a disposable device made of natural rubber material that bears powder to facilitate donning, and it is intended to be worn on the hands, usually in surgical setting, to provide a barrier against potentially infectious materials and other contaminants.

<table>
<thead>
<tr>
<th>Length</th>
<th>New Device Colour-way’s Glove</th>
<th>Predicate Device Powdered Latex Surgeon’s Glove (K062797)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5</td>
<td>250–280 mm</td>
<td>Min.245 mm</td>
</tr>
<tr>
<td>6</td>
<td>260–290 mm</td>
<td>Min.265 mm</td>
</tr>
<tr>
<td>6.5</td>
<td>260–290 mm</td>
<td>Min.265 mm</td>
</tr>
<tr>
<td>7</td>
<td>270–300 mm</td>
<td>Min.265 mm</td>
</tr>
<tr>
<td>7.5</td>
<td>270–300 mm</td>
<td>Min.265 mm</td>
</tr>
<tr>
<td>8</td>
<td>270–300 mm</td>
<td>Min.265 mm</td>
</tr>
<tr>
<td>8.5</td>
<td>280–310 mm</td>
<td>Min.265 mm</td>
</tr>
<tr>
<td>9</td>
<td>280–310 mm</td>
<td>Min.265 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Width</th>
<th>New Device Colour-way’s Glove</th>
<th>Predicate Device Powdered Latex Surgeon’s Glove (K062797)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5</td>
<td>72±4 mm</td>
<td>70 ± 6 mm</td>
</tr>
<tr>
<td>6</td>
<td>77±5 mm</td>
<td>76 ± 6 mm</td>
</tr>
<tr>
<td>6.5</td>
<td>83±5 mm</td>
<td>83 ± 6 mm</td>
</tr>
<tr>
<td>7</td>
<td>89±5 mm</td>
<td>89 ± 6 mm</td>
</tr>
<tr>
<td>Characteristics</td>
<td>New Device Colour-way's Glove</td>
<td>Predicate Device Powdered Latex Surgeon's Glove (K062797)</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------------------</td>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>Thickness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cuff</td>
<td>0.21±0.1 mm</td>
<td>Min. 0.10 mm</td>
</tr>
<tr>
<td>Palm</td>
<td>0.24±0.1 mm</td>
<td>Min. 0.10 mm</td>
</tr>
<tr>
<td>Finger</td>
<td>0.25±0.1 mm</td>
<td>Min. 0.10 mm</td>
</tr>
<tr>
<td>Before Ageing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tensile Strength</td>
<td>33~38 MPa</td>
<td>24MPa, min</td>
</tr>
<tr>
<td>Ultimate Elongation</td>
<td>750~800%</td>
<td>750% min</td>
</tr>
<tr>
<td>Stress at 500% Elongation</td>
<td>5.2~5.4MPa</td>
<td>5.5MPa, max</td>
</tr>
<tr>
<td>After Ageing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tensile Strength</td>
<td>28~34 MPa</td>
<td>18 MPa, min</td>
</tr>
<tr>
<td>Ultimate Elongation</td>
<td>740~810%</td>
<td>560%, min</td>
</tr>
<tr>
<td>Water Leak</td>
<td>Inspection Level: I</td>
<td>Inspection Level: I</td>
</tr>
<tr>
<td></td>
<td>AQL: 1.5</td>
<td>AQL: 1.5</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Guinea Pig Maximization</td>
<td>Gloves showed no significant evidence of causing skin sensitization as per ISO10993-10.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gloves showed no significant evidence of causing skin sensitization.</td>
</tr>
<tr>
<td></td>
<td>Primary Skin Irritation</td>
<td>Gloves are not irritating as per ISO10993-10.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gloves are not irritating.</td>
</tr>
<tr>
<td>Sterilization validation</td>
<td>Meet acceptance criteria as per ISO 11137-2.</td>
<td>Meet acceptance criteria</td>
</tr>
<tr>
<td>Labeling Features</td>
<td>Include the required labeling:</td>
<td>Surgeon's Gloves, Sterile, Disposable, Powdered,</td>
</tr>
<tr>
<td></td>
<td>Surgeon's Gloves, Sterile, Disposable, Powdered,</td>
<td></td>
</tr>
</tbody>
</table>
Based on the above comparison, the Colour-way Powdered Latex Surgeon’s Glove is equivalent to the predicate device with respect to technology characteristics such as material, design, intended use, specification and performance features. It is as safe and effective and performed as well as the referenced predicate device.

9. Clinical Data
Not Applicable

10. Conclusions
The Powdered Latex Surgeon’s Glove manufactured by Suzhou Colour-way Enterprise Development Co., Ltd and the predicate device meet the technology characteristics of ASTM D3577-09<sup>e</sup>, ISO10993-10:2010 and ISO11137-2:2012 standards. Besides, our Powdered Latex Surgeon’s Glove contains no more than 15mg/dm<sup>2</sup> powder and no more than 200μg/dm<sup>2</sup> extractable protein. Consequently, the device is substantially equivalent to the predicate device.
August 28, 2013

Suzhou Colour-Way Enterprise Development Company, Limited
Ms. Zhu Yingqiu
83 Changping Road
Dongqiao Industrial Area
Suzhou, Jiangsu
PR China 215152

Re: K121925
Trade/Device Name: Powdered Latex Surgeon’s Glove
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon’s Glove
Regulatory Class: I
Product Code: KGO
Dated: August 21, 2013
Received: August 26, 2013

Dear Ms. Yingqiu:

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" (21 CFR 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
Indications for Use Statement

510(k) Number (if known): K121925
Device Name: Powdered Latex Surgeon's Glove
Indications For Use: This Powdered Latex 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.

Prescription Use ______ AND/OR Over-The-Counter Use ______

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line-continue on another page of needed)

Concurrence of Center for Devices and Radiological Health (CDRH)

Sreekanth Gutala - S
2013.08.28 12:05:22.04'00'

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

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