



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

December 20, 2012

Mr. Alan Yu
Manager, Quality Assurance/Regulatory Affairs
Changzhou Holymed Products Company, Limited
528 Changwu Road South
Wujin District
Changzhou, Jiangsu, China 213167

Re: K121998
Trade/Device Name: HM Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: November 27, 2012
Received: November 29, 2012

Dear Mr. Yu:

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.

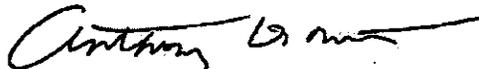
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/ucml15809.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,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K121998

Device Name: HM Surgical Gowns

Indications for Use:

HM Surgical gowns are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of micro-organisms, body fluids, and particulate matter.

HM Surgical Gowns are disposable, single use, sterile or nonsterile surgical gowns manufactured from non-woven Spunbond-Meltblown-Spunbond (SMS) polypropylene fabrics.

Non-sterile HM surgical gowns are to be sold to repackager/relabeler establishments for EtO sterilization according to ISO 11135-1 and Sterile surgical gowns are to be sold directly to users after EtO sterilization validation to ISO 11135-1.

Gowns are provided as below:

Gown Family A: 960100/860100

| PROD. CODE | STERILE/NONSTERILE | DESC. | SIZE | COLOR |
|------------|--------------------|-------------------------------|------|-------|
| 960102 | STERILE | Surgical Gown, Non Reinforced | M | BLUE |
| 960103 | STERILE | Surgical Gown, Non Reinforced | L | BLUE |
| 960104 | STERILE | Surgical Gown, Non Reinforced | XL | BLUE |
| 960105 | STERILE | Surgical Gown, Non Reinforced | XXL | BLUE |
| 860102 | NONSTERILE | Surgical Gown, Non Reinforced | M | BLUE |
| 860103 | NONSTERILE | Surgical Gown, Non Reinforced | L | BLUE |
| 860104 | NONSTERILE | Surgical Gown, Non Reinforced | XL | BLUE |
| 860105 | NONSTERILE | Surgical Gown, Non Reinforced | XXL | BLUE |

Gown Family B: 960200/860200

| PROD. CODE | STERILE/NONSTERILE | DESC. | SIZE | COLOR |
|------------|--------------------|----------------------------------|------|-------|
| 960202 | STERILE | Surgical Gown, Fabric Reinforced | M | BLUE |
| 960203 | STERILE | Surgical Gown, Fabric Reinforced | L | BLUE |
| 960204 | STERILE | Surgical Gown, Fabric Reinforced | XL | BLUE |
| 960205 | STERILE | Surgical Gown, Fabric Reinforced | XXL | BLUE |
| 860202 | NONSTERILE | Surgical Gown, Fabric Reinforced | M | BLUE |
| 860203 | NONSTERILE | Surgical Gown, Fabric Reinforced | L | BLUE |
| 860204 | NONSTERILE | Surgical Gown, Fabric Reinforced | XL | BLUE |
| 860205 | NONSTERILE | Surgical Gown, Fabric Reinforced | XXL | BLUE |

Gown Family C: 960300/86000

| PROD. CODE | STERILE/NONSTERILE | DESC. | SIZE | COLOR |
|------------|--------------------|--------------------------------|------------|-------|
| 960302 | STERILE | Surgical Gown, Poly Reinforced | M | BLUE |
| 960303 | STERILE | Surgical Gown, Poly Reinforced | L | BLUE |
| 960304 | STERILE | Surgical Gown, Poly Reinforced | XL | BLUE |
| 960306 | STERILE | Surgical Gown, Poly Reinforced | XL, X-Long | BLUE |
| 860302 | NONSTERILE | Surgical Gown, Poly Reinforced | M | BLUE |
| 860303 | NONSTERILE | Surgical Gown, Poly Reinforced | L | BLUE |
| 860304 | NONSTERILE | Surgical Gown, Poly Reinforced | XL | BLUE |
| 860306 | NONSTERILE | Surgical Gown, Poly Reinforced | XL, X-Long | BLUE |

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie

2012.12.19 21:51:29 -05'00'

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

510(k) Number: 121 998