



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

December 12, 2012

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

Re: K122000

Trade/Device Name: HM Surgical Drapes, HM Surgical Equipment Covers  
Regulation Number: 21 CFR 878.4370  
Regulation Name: Surgical Drape and Drape Accessories  
Regulatory Class: II  
Product Code: KKK  
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/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" (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,



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): K122000

Device Name: HM Surgical Drapes

### Indications for Use:

HM surgical drapes are intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.

HM surgical drapes are disposable, single use, sterile or nonsterile.

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

Drapes are provided as below

Drape Model Family	Drape Name	Model Code (Sterile/Nonsterile)	Color	Drape Materials
Angiography Drapes	Angiography Surgical Drape	935101/835101	Blue	SMS base panel with SM pad and polyethylene sides
Fenestrated Drape	Clear Legging Surgical Drape	935201/835201	Clear	Polyethylene Film
Extremity Drapes	Universal Extremity Surgical Drape	935301/835301	Blue	SMS base panel with SM pad
	Legging Surgical Drape	935302/835302	Blue	SMS panel
	Head Surgical Drape	935303/835303	Blue	SMS panel
	Side Surgical Drape	935304/835304	Blue	SMS base panel with SM pad
	Top Surgical Drape	935305/835305	Blue	SMS base panel with SM pad
	Bottom Surgical Drape	935306/835306	Blue	SMS base panel with SM pad
	Bar Surgical Drape	935307/835307	Blue	SMS base panel with SM pad
Laparotomy Drapes	Laparotomy Surgical Drape	935401/835401	Blue	SMS base panel with SM pad
Arthroscopy Drapes	Arthroscopy Surgical Drape	935501/835501	Blue	SMS base panel with SM Pad and polyethylene pouch
Under buttocks Drapes	Under buttocks Surgical Drape	935601/835601	Blue	SMS base panel with SM Pad and polyethylene pouch
Split Drapes	Split Surgical Drape	935701/835701	Blue	SMS base panel with SM pad
Lithotomy Drapes	Lithotomy Surgical Drape	935801/835801	Blue	SMS base panel with SM pad
Laparoscopic Drapes	Laparoscopic Surgical Drape	935901/835901	Blue	SMS base panel with SM pad
Thyroid Drapes	Thyroid Surgical Drape	936001/836001	Blue	SMS base panel with SM pad
Abdominal Drapes	Abdominal Surgical Drape	936101/836101	Blue	SMS panel
C-section Drapes	C-section Surgical Drape	936201/836201	Blue	SMS base panel with polyethylene pouch
Minor Procedure Drapes	Minor Procedure Surgical Drape	936301/836301	Blue	SMS base panel with SM pad
Lap Chole Drape	Lap Chole Surgical Drape	936401/836401	Blue	SMS base panel with SM pad
Universal Spine Drape	Universal Spine Surgical Drape	936501/836501	Blue	SMS base panel with SM pad
Cystoscopy T Surgical Drape	Cystoscopy T Surgical Drape	936601/836601	Blue	SMS base panel with SM pad
Chest Surgical Drape	Chest Surgical Drape	936701/836701	Blue	SMS base panel with SM pad
Utility Surgical Drape	Utility Surgical Drape	936801/836801	Blue	SM absorbent panel
Ophthalmic Drapes	Ophthalmic Surgical Drape	936901/836901	Blue	SMS base panel with

Cardiac Drapes	Cardiac Surgical Drapes	Blue	SM absorbent panel with polyethylene backing
Aperture Surgical Drapes	Aperture Surgical Drapes	Blue	SM absorbent panel with a polyethylene backing

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   X    
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: \_\_\_\_\_

**INDICATIONS FOR USE**

510(k) Number (if known): K122000

Device Name: HM Surgical Equipment Covers

**Indications for Use:**

HM Surgical Equipment Covers are intended to be used to cover surgical equipment and provide a protective barrier for that equipment.

HM surgical equipment covers are disposable, single use, sterile or nonsterile.

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

Drapes are provided as below

Drape Model Family	Equipment Cover Name	Model Code (Sterile/Nonsterile)	Cover	Drape Materials
Equipment Cover	Band Bag	938101/838101	Clear	Polyethylene bag
	Mayo Stand Cover	938102/838102	Blue	Blue polyethylene tube with SM reinforcement
	Table Cover	938103/838103	Blue	Blue polyethylene film with SM reinforcement

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   X    
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie

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

510(k) Number: \_\_\_\_\_