



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

November 17, 2014

Cobes Industries Company Limited  
C/O Ms. Lynn Fu  
Shenzhen Rendermed Consulting Company Limited  
23 Dengliang Road, Hanking Center 7E-011  
Shenzhen, Gguangdong 518052  
CHINA

Re: K141606  
Trade/Device Name: Surgical Gown  
Regulation Number: 21 CFR 878.4040  
Regulation Name: Surgical Apparel  
Regulatory Class: II  
Product Code: FYA  
Dated: October 11, 2014  
Received: October 17, 2014

Dear Ms. Fu:

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,

A handwritten signature in black ink that reads "Susan Runna DDS, MA". The signature is written in a cursive style. A faint, semi-transparent watermark of the FDA logo is visible behind the signature.

Erin I. Keith, M.S.  
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)  
K141606

Device Name

Surgical Gown

Indications for Use (Describe)

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 transfer of microorganisms, body fluids, and particulate material.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

Product Models are provided below:

Model Category	Model	Size	Reinforced method	Material
21Series	21001	Large	Non-Reinforced	SMS-35gsm
	21002	X-Large		
	21003	XX-Large		
	21004	XXX-Large		
	21101	Large	Fabric Reinforced	
	21102	X-Large		
	21103	XX-Large		
	21201	Large	Poly-Reinforced	
	21202	X-Large		
	21203	XX-Large		
	21204	XXX-Large		
	21205	XXXX-Large		
	21206	XXXXX-Large		
	21301	Large	Poly-Reinforced, Breathable Trilaminate Sleeves	
21302	X-Large			
21303	XX-Large			
21304	XXX-Large			
22Series	22001	Large	Non-Reinforced	SMS-47gsm
	22002	X-Large		
	22003	XX-Large		
	22004	XXX-Large		
	22005	XXXX-Large		
	22101	Large	Fabric Reinforced	
	22102	X-Large		
	22103	XX-Large		
	22201	Large	Poly-Reinforced	
	22202	X-Large		
	22203	XX-Large		
	22204	XXX-Large		
	22205	XXXX-Large		
	22301	Large	Poly-Reinforced, Breathable Trilaminate Sleeves	
22302	X-Large			
22303	XX-Large			
23Series	23001	Large	Non-Reinforced	SMS-47gsm soft
	23002	X-Large		
	23003	XX-Large		
	23004	XXX-Large		
	23101	Large	Fabric Reinforced	
	23102	X-Large		
	23103	XX-Large		
	23201	Large	Poly-Reinforced	
	23202	X-Large		
	23203	XX-Large		
	23204	XXX-Large		
	23205	XXXX-Large		
	23206	XXXXX-Large		
	23301	Large	Poly-Reinforced, Breathable Trilaminate Sleeves	
23302	X-Large			
23303	XX-Large			
23304	XXX-Large			

Model Category	Model	Size	Reinforced method	Material
24Series	24001	Large	Breathable Trilaminate Sleeves	SFS-68gsm
	24002	X-Large		
	24003	XX-Large		
	24004	XXX-Large		
	24005	XXXX-Large		
	24006	XXXXX-Large		

First code:	Second code	Third code	Fourth-Fifth code
2-Surgical Gown	1- SMS-35gsm	0- Non-Reinforced	01-Large
	2- SMS-47gsm	1- Fabric Reinforced	02-X-Large
	3-SMS-47gsm Soft	2- Poly-Reinforced	03- XX-Large
	4- SFS-68gsm	3-Poly-Reinforced, Breathable Trilaminate Sleeves	04- XXX-Large
		4- Non-Reinforced, Breathable Viral Barrier	05-XXXX-Large
			06-XXXXX-Large