February 15, 2018

Jingzhou Haixin Green Cross Medical Products Co., Ltd
% Raymond Luo
Technical Manager
Shanghai Sungo management Consulting Company Limited
4th Floor, 1500# Central Avenue
Shanghai, 200122 China

Re: K171535
Trade/Device Name: Surgical Isolation Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: January 9, 2018
Received: January 11, 2018

Dear Raymond Luo:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171535

Device Name
SURGICAL ISOLATION GOWN

Indications for Use *(Describe)*
The Surgical Isolation Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, the Surgical Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70).The Surgical Isolation Gown is a single use, disposable medical device provided non-sterile.

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.

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510(K) Summary

K 171535
Date of preparation: 2018-1-25

A. Applicant:

Name: Jingzhou Haixin Green Cross Medical Products Co., Ltd

Address: Room 916-918, Floor 9, International Finance Center, No.296, Xinhua Road, Wuhan City, Hubei Province, China

Official Contact Person Information

Name: Raymond Luo
Tel: 0086-21-68828050
Mail: fda.sungo@gmail.com
Shanghai Sungo Management Consulting Co., Ltd.

B. Device:

The proprietary name of the new device: SURGICAL ISOLATION GOWN
Common Name: Isolation Gown
Classification Name: Surgical Isolation Gown
Classification regulation: 21 CFR 878.4040
Classification: Class II.
Regulation Name: Surgical Apparel
Product code: FYC

C. Predicate device:

K160339
Cardinal Health™ Isolation Gown
Cardinal Health 200, LLC

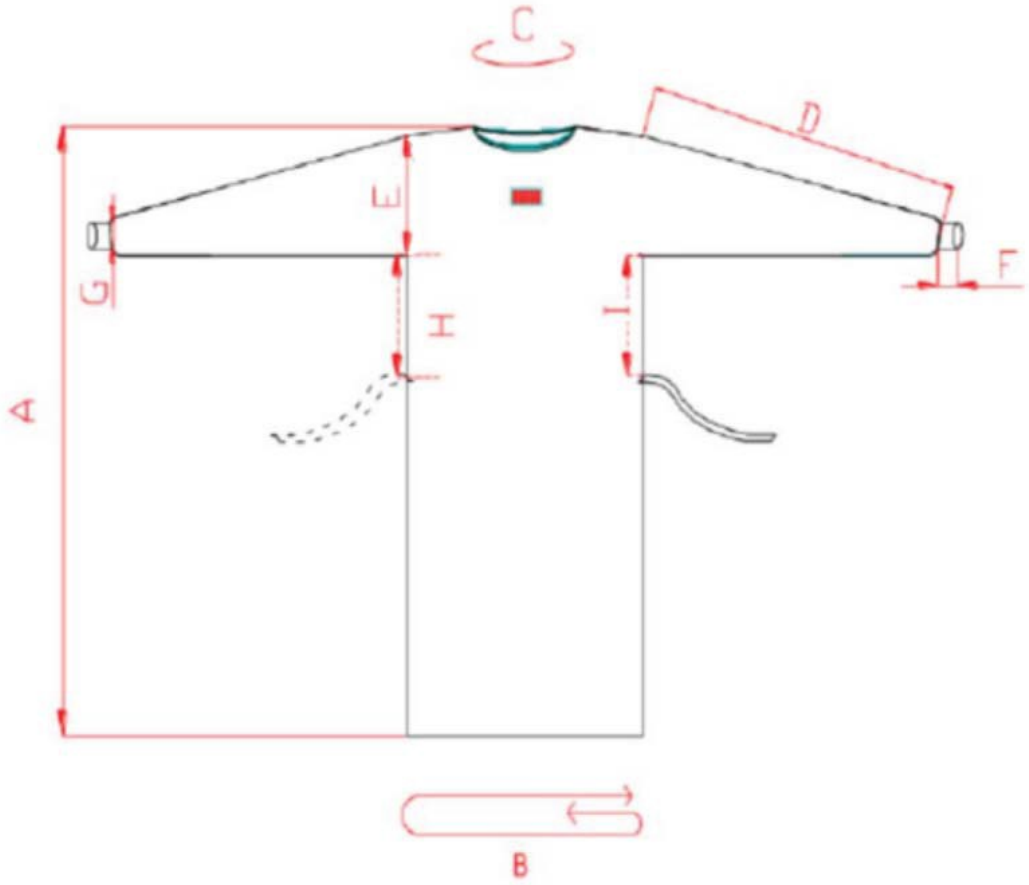
D. Indications for use:

The Surgical Isolation Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, the Surgical Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Surgical Isolation Gown is a single use, disposable medical device provided non-sterile.

E. Device Description

The proposed SURGICAL Isolation Gown is constructed of polyolefin (Polypropylene) SMS nonwoven material with the color in yellow. The SURGICAL Isolation Gowns consist of a one critical zone throughout the entire gown including seams but excluding cuffs, hems, and bindings. The product has been tested for barrier performance per ANSI/AAMI PB70:2012. Testing was performed according to the

Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, issued on August 1, 1993 and ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities. All results of testing met AATCC-42/AATCC-127, and meets AAMI PB70:2012 Level 3 requirements.



Size	Measurement Location (cm)							
	A	B	C	D	E	F	G	H/I
Universal	119	138	22	62	31	7.5	13	24
XL	125	146	24	68	33	7.5	14.5	24.5
XXL	133	160	30	72	36	7.5	16	25

F. Comparison with predicate

Device	K171535	K160339	Comparison
Manufacturer	Jingzhou Haixin Green Cross Medical Products Co., Ltd	Cardinal Health 200, LLC	NA
Model Name	SURGICAL ISOLATION GOWN	Cardinal Health™	NA
Classification	Class II Device, FYC (21 CFR878.4040)	Class II Device, FYC (21 CFR878.4040)	Same
Intend use	The Surgical Isolation Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, the Surgical Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Surgical Isolation Gown is a single use, disposable medical device provided non-sterile.	Cardinal Health Isolation Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, The Cardinal Health Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Cardinal Health Isolation Gown is a single use, disposable medical device provided non-sterile.	Similar

Description	The Surgical Isolation Gown is a surgical isolation gown with moderate barrier protection identified by Regulation 21 CFR 878.4040 under FDA product code, FYC. The Surgical Isolation Gown is a single use, disposable medical device provided non-sterile. The Surgical Isolation Gown is offered in yellow with three sizes. Each model is constructed of a non-woven material and has been tested according to ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities and meets AAMI Level 3.	The Surgical Isolation Gown is a surgical isolation gown with moderate barrier protection identified by Regulation 21 CFR 878.4040 under FDA product code, FYC. The Surgical Isolation Gown is a single use, disposable medical device provided non-sterile. The Surgical Isolation Gown is offered in two color (blue and yellow) models and each model is offered in two sizes for a total of four models. Each model is constructed of a non-woven material and has been tested according to ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities and meets AAMI Level 3.	Similar
Material	Polypropylene SMS non woven	Polypropylene SMS non woven	Same

Composition			
Design Features	Medical Tape Neck Closure White Belt Tie Snap fastener	Medical Tape Neck Closure White Belt Tie Elastic Cuffs	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Color	Yellow	Blue and Yellow	Similar

Element of Comparison	**K171535**	**K160339**	**Comparison**
Basis weight (oz/yd2) ASTM D3776	Testing not performed	Mean = 1.21 Ind Min = 1.19 Ind Max = 1.23	NA
Grab tensile MD (lb) ASTM D5034	Mean = 20.71 Ind Min = 19.73 Ind Max = 21.87	Mean = 24.38 Ind Min = 21.94 Ind Max = 26.28	Similar
Grab tensile CD (lb) ASTM D5034	Mean = 12.21 Ind Min = 11.20 Ind Max = 14.11	Mean = 14.54 Ind Min = 12.70 Ind Max = 16.45	Similar
Trap Tear MD, (lbs) ASTM D5587-15 Highest Peak	Mean = 3.48 Ind Min = 2.82 Ind Max = 3.93	Mean = 4.74 Ind Min = 3.67 Ind Max = 5.47	Similar
Trap Tear CD, (lbs) ASTM D5587-15 Highest Peak	Mean = 7.15 Ind Min = 6.20 Ind Max = 7.70	Mean = 9.24 Ind Min = 7.54 Ind Max = 12.98	Similar
Flammability CPSC, Part 1610	Class I	Class I	Same
Hydrostatic Head (cm) AATCC 127	CHEST/BACK/SLEEVE: Mean = 69 Ind Min = 54 Ind Max = 84	Body/Sleeve: Mean = 69 Ind Min = 56 Ind Max = 84	Similar
Water Impact (g) AATCC-42 (performed with water per AATCC42:2013)	Sleeve Seams: Mean = 0.04 Ind Min = 0.02 Ind Max = 0.08 CHEST: Mean = 0.04 Ind Min = 0.02 Ind Max = 0.05 Back: Mean = 0.05 Ind Min = 0.04 Ind Max = 0.07	N/A Body/Sleeve: Mean = 0.08 Ind Min = 0.05 Ind Max = 0.13	Similar
Liquid Barrier Performance	Device was tested in	Device was tested in	Same

Classification Properties	accordance with ANSI/AAMI PB70:2012 and meets Level 3 requirements for an isolation gown. The critical zone areas tested were the chest, the back, the sleeve seam, the belt seam and side seam.	accordance with ANSI/AAMI PB70:2012 and meets Level 3 requirements for an isolation gown. The critical zone areas tested were the body and sleeve (same fabric), the sleeve seam, front belt or tie attachment, and the front seam arm attachment using multiple lots.	
Biocompatibility	The test was done against ISO10993-5 and ISO10993-10. The result indicates the gown is noncytotoxic, non-irritating, and non-sensitizing per ISO 10993-1.	Under the conditions of each study, the Cardinal HealthTM Isolation gown is noncytotoxic, non-irritating, and non-sensitizing per ISO 10993-1.	Same
Sterilization Modality	None (Non-Sterile)	None (Non-Sterile)	Same
Lint and other particles generated in dry state	SIDE A: OUTSIDE TOTAL >0.3 1024 TOTAL >0.5 658 SIDE B: INSIDE TOTAL >0.3 1066 TOTAL >0.5 697	Performance values not available in predicate 510(k) submission	NA

G. Summary of Non-clinical tests

The SURGICAL Isolation gowns are substantially equivalent to the predicate device, in terms of general intended use, performance testing, material composition, and configuration/dimensions. Under the conditions of each study, the SURGICAL Isolation gown is non-cytotoxic, nonirritating, and non-sensitizing per ISO-10993 and have met the requirements of ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities for an AAMI Level 3 isolation gown.

H. Conclusion

The Surgical Isolation Gowns are as safe, as effective and performs as well as the legally marketed device identified in this submission.