January 16, 2019

Xiantao Rayxin Medical Products Co., Ltd.
Mr. Ray Wang
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
BeiJing, 102401 Cn

Re: K173847
Trade/Device Name: Disposable Ultra Reinforced Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: December 4, 2018
Received: December 7, 2018

Dear Ray Wang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Clarence W. Murray Iii III -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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K173847

Device Name
Disposable Ultra Reinforced Surgical Gown

Indications for Use *(Describe)*
The Disposable Ultra Reinforced Surgical Gown is intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. It is single use, disposable medical devices, provided 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.

***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."*

# 510(k) Summary

This 510(k) Summary is being submitted in accordance with Title 21 CFR Section 807.92.

The assigned 510(k) Number: K173847

1. Date of Preparation:2019/01/16

2. Sponsor Identification

**Xiantao Rayxin Medical Products Co., ltd.**
No. 258 Pengchang Road, Middle Street, Xiantao city, Hubei 433018, China

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3. Designated Submission Correspondent

Mr. Ray Wang

**Beijing Believe-Med Technology Service Co., Ltd**

Email: Ray.Wang@believe-med.com

4. Identification of Predicate Device(s)

Predicate Device
K170762
Cardinal Health Surgical Gown
Cardinal Health 200, LLC

5. Identification of Proposed Device

Trade Name: Disposable Ultra Reinforced Surgical Gown
Common Name: Surgical Gown
Model(s): S, M, L, XL

Regulatory Information
Classification Name: Surgical Gown
Classification: 2
Product Code: FYA
Regulation Number: 878.4040
Review Panel: General & Plastic Surgery

Device Description
The Disposable Ultra Reinforced Surgical Gown is reinforced surgical gown, which is comprised of a single layer blue non-woven fabric SMS, and an additional layer of SMS in critical zones of sleeve and front chest. It has been tested according to AAMI PB70:2012 and meet AAMI Level 3 barrier level protection for a surgical gown.
The subject devices are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate materials.

In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

The proposed devices are single use, disposable medical devices and provided sterile.

Indication for use Statement:
The ***Disposable Ultra Reinforced Surgical Gown*** is intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. It is single use, disposable medical devices, provided sterile

6. Technological Characteristic Comparison Table

Table 1 General Comparison

| ITEM | Proposed Device | Predicate Device<br>K170762 | Comparison |
|---|---|---|---|
| Intended Use | ***Disposable Ultra Reinforced Surgical Gown*** is intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. It is single use, disposable medical devices, provided sterile | Cardinal Health™ Non-Reinforced Surgical Gown is intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). The Cardinal Health™ Non-Reinforced Surgical Gowns are single use, disposable medical devices; provided sterile and non-sterile. | SAME |
| Material | SMS polypropylene nonwoven | SMS polypropylene nonwoven | SAME |
| Use | Single Use; Disposable | Single Use; Disposable | SAME |
| Sterility | Sterile | Sterile and non-sterile | SAME |
| Color | Blue | Blue | SAME |
| Weight per square (g) | 44 $g/m^2$ | 31g/ $m^2$ (1.32 $oz/yd^2$) | Similar |
| Tensile | MD Mean ≥30 lbs;<br>CD Mean≥25 lbs | MD Mean 21.57 lbs<br>CD Mean 13.6 lbs | Similar |

| | | | |
|---|---|---|---|
| Tear | MD Mean ≥9 lbs;<br>CD Mean≥18 lbs | MD Mean 3.47 lbs<br>CD Mean 5.63 lbs | Similar |
| Flammability (sec.)<br>CPSC, Part 1610 | Class I | Class I | SAME |
| Hydrostatic Pressure (cm)<br>AATCC-127 | >50 cm | >50 cm | SAME |
| Water Impact (g)<br>AATCC-42 | ≤1.0 g | ≤1.0 g | SAME |
| Resistance to blood and liquid penetration | Level 3 AAMI PB70 | Level 3 AAMI PB70 | SAME |
| Biocompatibility | Under the conditions of the study, the device extract was not cytotoxic.<br>Under the conditions of the study, the non-polar and polar device extracts were not found to be an irritant.<br>Under conditions of the study, the non-polar and polar device extracts were not found to be a sensitizer. | | SAME |
| Sterilization Method & SAL | Ethylene Oxide (EO), SAL=$10^{-6}$<br>The EO/ECH residues meet the requirements of ISO 10993-7 | Ethylene Oxide (EO), SAL=$10^{-6}$<br>The EO/ECH residues meet the requirements of ISO 10993-7 | SAME |
| Size | S, M, L, XL | M-S, M, L, XL, XXL | SAME |

Analysis: The proposed device has same or better performance to the predicate device. So we consider which is same with the predicate.

7. Summary of Non-Clinical Performance Test

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device met its acceptance criteria or testing endpoint safe levels using the following standards:

- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-7: 2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ASTM F2407-06, Standard Specification For Surgical Gowns Intended For Use In Healthcare Facilities.
- CPSC 16 CFR Part 1610-2008, Standard for the Flammability of clothing textiles;
- AATCC 127-2014, Water Resistance: Hydrostatic Pressure Test;
- AATCC 42-2013, Water Penetration Resistance: Impact Penetration Test;
- ASTM D5034-09, Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test);
- ASTM D5587-15, Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure;
- AAMI/ANSI PB70:2012, Liquid Barrier Performance and Classification of protective Apparel and Drapes Intended For Use In Health Care Facilities.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion:

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K170762.