April 29, 2022

Crown Name Disposable Hygiene Products Fty.Ltd.
℅ Doris Chen
Regulatory Affairs Staff
Shanghai Jiushun Enterprise Management Technology Service Co
Room 1502,BaoAn Buiding,No.800 Dongfang Road
Shanghai, 200122
China

Re: K212422
Trade/Device Name: Disposable Surgical Isolation Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: March 28, 2022
Received: April 1, 2022

Dear Doris Chen:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian, M.D., Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K212422

Device Name
Disposable Surgical Isolation Gown
Model:CN302

Indications for Use *(Describe)*
The Disposable Surgical Isolation Gown is intended to protect 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 disposable surgical isolation gown meets the requirements of a Level 4 barrier protection per ANSI/AAMI PB70:2012 - Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities. The disposable 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.

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

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# 510(k) Summary K212422

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) Number: K212422

Summary Prepared Date:March 28, 2022

**1. Submitter Information**

- Sponsor Name: Crown Name Disposable Hygiene Products Fty. Ltd.
- Address: Chengbei Industrial Zone,Zhucheng Ave,Xinzhou District,Wuhan,Hubei, 431400,CHINA.
- Contact Person (including title): Ying Fang (Manger)
- Phone:+86-27-82761940
- Fax: +86-27-82761339

**2. Submission Correspondent:**

- Contact Person: Doris Chen
- Shanghai Jiushun Enterprise Management Technology Service Co., Ltd.
- Address: Room 1502,BaoAn Buiding,No.800 Dongfang Road,Shanghai,China.
- Tel: +86-21-50931939
- Email: doris-chen@isosh.com

**3. Subject Device Information**

| | |
|---|---|
| Type of 510(k): | Traditional |
| Common Name: | Surgical Apparel |
| Trade Name: | Disposable Surgical Isolation Gown |
| Classification Name: | Gown, Isolation, Surgical |
| Review Panel: | General Hospital |
| Product Code: | FYC |
| Regulation Number: | 21 CFR 878.4040 |
| Regulation Class: | II |

## 4. Predicate Device Information

**Predicate Device**

| | |
|---|---|
| Sponsor: | Yanbian Pacific Textile Co., LTD |
| Common Name: | Surgical Apparel |
| Trade Name: | Surgical Isolation Gown |
| 510(k) number: | K203415 |
| Review Panel: | General Hospital |
| Product Code: | FYC |
| Regulation Number: | 21 CFR 878.4040 |
| Regulation Class: | II |

## 5. Device Description

The disposable surgical isolation gown consist of a one critical zone throughout the entire gown including seams but excluding cuffs, hems, and bindings,The products are composed of 45g of SMS (spunbond, meltblown, spunbond) non-woven fabric and 20g of PE(Polyethylene) film layer material with the color in blue.Disposable surgical isolation gown have a hook and loop fastener at the back of the neck and a waist ties feature to secure the gown to the body of the user. The material of the collar of the Disposable Surgical Isolation Gown is 35g of white PP (polypropylene). The cuffs are white polyester rib sleeve cloth with a length of 7.5cm. The disposable surgical isolation gown provided in ONE product model in six sizes.The size of disposable surgical isolation gown is divided into six groups: S, M, L, XL, XXL, XXXL.

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the disposable surgical isolation gown meet the requirements for Level 4 classification.

The disposable surgical isolation gown is a single use, disposable medical device provided non-sterile.

## 6. Intended Use / Indications for Use

The Disposable Surgical Isolation Gown is intended to protect 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 disposable surgical isolation gown meets the requirements of a Level 4 barrier protection per ANSI/AAMI PB70:2012 -Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities. The disposable surgical isolation gown is a single use, disposable medical device provided non-sterile.

## 7. Comparison with predicate device

Table 1 General Comparison

| **Elements of Comparison** | **Subject Device** | **Predicate Device** | **Verdict** |
|---|---|---|---|
| Manufacturer | Crown Name Disposable Hygiene Products Fty.Ltd. | Yanbian Pacific Textile Co., LTD | -- |
| Product Name | Disposable Surgical Isolation Gown | Surgical Isolation Gown | -- |
| K Number | K212422 | K203415 | -- |
| Product Code | FYC | FYC | Same |
| Regulation Number | 21 CFR 878.4040 | 21 CFR 878.4040 | Same |
| Intended use/ Indications for Use | The Disposable Surgical Isolation Gown is intended to protect 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 disposable surgical isolation gown meets the requirements of a Level 4 barrier protection per ANSI/AAMI PB70:2012 -Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities. The disposable surgical isolation gown is a single use, disposable medical device provided non-sterile. | The Surgical Isolation Gown is intended to protect 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. | Similar |

| | | | |
|---|---|---|---|
| Barrier protection level | Level 4 per AAMI PB 70 | Level 3 per AAMI PB 70 | Different Note 1 |
| Gown Style | Hook and loop Closure,Belt Tie, Elastic Cuffs | Tape Neck Closure ,Belt Tie,Elastic Cuffs | Similar Note 3 |
| Durability | Disposable | Disposable | Same |
| OTC Use | Yes | Yes | Same |
| Sterile | No | No | Same |
| Size | S, M, L, XL, XXL, XXXL. | S, M, L, XL, XXL, 3XL, 4XL | Similar |
| Color | Blue | Blue | Same |
| Material Composition | SMS Nonwoven,Polyethylene, Polyester,Polypropylene,Nylon | SMS PP + PE non-woven fabric material | Similar Note 2 |
| Weight per square (g) (ASTM D3776) | 66g/$m^2$ | 60.7g/$m^2$ (1.79 oz/yd2) | Similar Note 3 |
| Flammability (16 CFR Part 1610) | Class I<br>(Results obtained from Three Lots) | Class I | Same |
| Liquid Barrier Performance (AAMI PB70) | (Results obtained from Three Lots)<br>Hydrostatic Pressure(cm)<br>:>50cm $H_2O$<br>(AATCC-127) | Hydrostatic Pressure(cm)<br>:>50cm $H_2O$<br>(AATCC-127) | Same |
| | Water Impact (g)：≤1.0g<br>(AATCC-42) | Water Impact (g)：≤1.0g<br>(AATCC-42) | Same |
| | Resistance by Blood-Borne Pathogen:<br>1: Base Material: Pass<br>2:Seam:Pass<br>3:Sleeve seam:Pass<br>Assay titer (PFU/mL):All were<1<br>(ASTM F1671/F1671M-2013) | Unknown | Different Note 4 |
| Breaking Strength (ASTM D5034) | Lot A:<br>(Length:191.46N/Width:135.46N)<br>Lot B:<br>(Length:193.88N/Width:131.52N)<br>Lot C:<br>(Length:190.76N/Width:135.48N) | Breaking Strength(MD)：<br>(Mean: 175.5N)<br>Breaking Strength(CD)：<br>(Mean: 118.0N) | Similar Note 4 |
| Tearing Strength (ASTM D5733) | Lot A:<br>(Length:83.92N/Width:54.42N)<br>Lot B:<br>(Length:89.02lbf/Width:57.96N) | Tearing strength (MD):<br>Mean: 63.5N<br>Tearing strength (CD):<br>Mean: 34.5N | Similar Note 4 |

| | | | |
|---|---|---|---|
| | Lot C:<br>(Length:20.32lbf/Width:12.3lbf) | | |
| Linting<br>(EN ISO 9073-10) | Lot A:<br>1.Material(Mean):2.6(Face A/B)<br>2.Sleeve seam(Mean):2.6(Face A/B)<br>Lot B:<br>1.Material(Mean):2.9(Face A/B)<br>2.Sleeve seam(Mean):3.0(Face A/B)<br>Lot C:<br>1.Material(Mean):2.9(Face A/B)<br>2.Sleeve seam(Mean):2.9(Face A/B)<br>($Log_{10}$<4)<br>(Results obtained from Three Lots) | Particulate size range(μm):<br>3 to 25<br>A: Face: Measured value<br>Coefficient of lingting log10<br>Min:2.2, Max:2.8,<br>Mean: 2.5;<br><br>B: Face: Measured value<br>Coefficient of lingting log10<br>Min:2.5, Max:2.9,<br>Mean:2.74 | Similar<br>Note 4 |
| Seam Strength<br>(ASTM D1683) | Lot A: 22.14lbf(FTS)<br>Lot B: 20.6lbf(FTS)<br>Lot C:21.4lbf(FTS) | Unknown | Different<br>Note 5 |
| Air permeability<br>(ASTM D737) | 0.065$cm^3/cm^2$/sec<br>(Results obtained from Three Lots) | Unknown | Different<br>Note 5 |
| Thermal and Evaporative Resistance<br>(ASTM F1868) | Evaporative Resistance:<br>Arithmetic Mean:0.089kPa.$m^2$/W | Unknown | Different<br>Note 5 |
| | Intrinsic Evaporative<br>Arithmetic Mean:0.085kPa.$m^2$/W | | |
| Biocompatibility | | | |
| Cytotoxicity | Under the conditions of the study, the device is noncytotoxic. | Under the conditions of the study, the device is noncytotoxic. | Same |
| Sensitization | Under the conditions of the study, the device is nonsensitizing | Under the conditions of the study, the device is nonsensitizing | Same |
| Irritation | Under the conditions of the study, the device is nonirritating. | Under the conditions of the study, the device is nonirritating. | Same |

Note: “unknown” above indicates performance values were not available in predicate 510(k) submissions.

**Note 1**

The barrier protection level of the subject device is different from the predicate device,but the test results of they are both meet the requirement of surgical isolation gown's barrier protection level according to the AAMI PB70.Therefore, this different will not raise new safety and effectiveness questions.

**Note 2**

The material of the subject device is different from the predicate device. There are not raise additional questions for safety and effectiveness.

The biocompatibility evaluation test of the subject devices have been performed on the final finished device. The test results shows pass the requirements. There is no new risk generated from the difference of the material.

**Note 3**

Compare with the subject device and predicate device, the different of the physical feature(Weight Per Unit Area,Gown style) does not affect the intended use of the subject device.Therefore, this different will not raise new safety and effectiveness questions.

**Note 4**

For the performance testing of liquid barrier performance,breaking strength,tearing strength, seam strength and linting level,the test results of the subject device and the predicate device are not identical to each other, but they are similar and both meet the requirements of the acceptance standards of their corresponding performance testing standards.Therefore, this different will not raise new safety and effectiveness questions.

**Note 5**

Although the seam strength,air permeability, thermal and evaporative resistance of the predicate devices are unknown, the seam strength,air permeability,thermal and evaporative resistance of the subject device all meet the corresponding standard requirements and can be used safely. Therefore, this different will not raise new safety and effectiveness questions.

## 8. Summary of Non-Clinical Tests Performed

Non-clinical tests were conducted to verify that the proposed device met all design specifications as to the predicate device. The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes:

- ASTM- F2407-20 Standard Specification for Surgical Gowns intended for Use in Healthcare Facilities
- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles.
- ASTM F1671/F1671M-2013 Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne.
- AATCC 42-2017e-Water Penetration Resistance:Impact Penetration Test.
- AATCC 127-2017(2018)-Water Resistance:Hydrostatic Pressure Test.
- ISO 9073-10:2004 Textiles-Test Methods for Nonwovens-Part 10: Lint and Other Particles Generation in the Dry State.
- ASTM D1683/D1683M:2017/(R)2018 Standard Test Method for Failure in Sewn Seams of Woven Fabrics.
- ASTM D5733:1999 Standard Test Method For Tearing Strength of Nonwoven Fabrics By The Trapezoid Procedure.
- ASTM D5034-09 (2017) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test).
- ASTM D737:2018 Standard Test Method for Air Permeability of Textile Fabrics.
- ASTM D3776/D3776M-09a(2017) Basis Weight-Mass Per Unit Area (Weight) of Fabric.
- ASTM F1868−17 Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate.
- 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.

Table 2:Performance Testing

| **Test item** | **Proposed device** | **Acceptance criteria** | **Results** |
|---|---|---|---|
| Weight per square (g) (ASTM D3776) | 3 non-consecutive lots tested<br>Lot A: 66.88 g/m²<br>Lot B: 67.86 g/m²<br>Lot C: 66.92g/m² | ≥65g/m² | Pass |
| Flammability (16 CFR Part 1610) | Class1<br>3 non-consecutive lots tested | Class 1:Burn time≥3.5 seconds | Pass |
| Liguid Barrier Performance AATCC-127 | 3 non-consecutive lots tested, using a sample size of 32/lot.<br>Hydrostatic Pressure(cm) :>50cm $H_2O$ | Hydrostatic Pressure(cm) : >50cm $H_2O$ | Pass |
| Liguid Barrier Performance (AATCC-42) | 3 non-consecutive lots tested, using a sample size of 32/lot.<br>Water Impact (g)：≤1.0g | Water Impact (g)：≤1.0g | Pass |
| Liguid Barrier Performance (ASTMF1671/F1671M -2013) | 3 non-consecutive lots tested, using a sample size of 32/lot.<br>Resistance t by Blood-Borne Pathogen:<br>1: Base Material: Pass<br>2:Seam:Pass<br>3:Sleeve seam:Pass<br>Assay titer (PFU/mL):All were<1 | 1.Assay titer (PFU/mL)<1<br>2.29 out of 32 pass at 13.8kPa(1min) | Pass |
| Tensile Strength (ASTM D5034) | Lot A: (Length:42.94lbf/Width:30.4lbf)<br>Lot B: (Length:43.5lbf/Width:29.5lbf)<br>Lot C:(Length:42.64lbf/Width:30.38lbf) | ≥7lbf | Pass |
| Tearing Strength (ASTM D5733) | Lot A: (Length:18.82lbf/Width:12.2lbf)<br>Lot B: (Length:19.94lbf/Width:12.98lbf)<br>Lot C:(Length:20.32lbf/Width:12.3lbf) | ≥2.3 lbf | Pass |
| Seam Strength (ASTM D1683) | Lot A: 22.14lbf(FTS)<br>Lot B: 20.6lbf(FTS)<br>Lot C:21.4lbf(FTS) | ≥7 lbf | Pass |
| Linting (EN ISO 9073-10) | $Log_{10}$<4(Material/Sleeve)<br>(Results obtained from Three Lots) | $Log_{10}$<4 | Pass |
| Air permeability (ASTM D737) | 0.065cm³/cm²/sec<br>(Results obtained from Three Lots) | -- | Pass |

| | | | |
|---|---|---|---|
| Evaporative Resistance of Clothing Materials (ASTM F1868) | Lot A:<br>Evaporative Resistance:<br>Arithmetic Mean:0.08981kPa.m2/W<br>Intrinsic Evaporative Arithmetic Mean:0.08638kPa.m2/W<br>Lot B:<br>Evaporative Resistance (Ret)<br>Arithmetic Mean:0.08666kPa.m2/W"<br>Intrinsic Evaporative Arithmetic Mean:0.08323kPa.m2/W"<br>Lot C:<br>Evaporative Resistance (Ret)<br>Arithmetic Mean:0.08971kPa.m2/W"<br>Intrinsic Evaporative Arithmetic Mean:0.08628kPa.m2/W" | -- | Pass |

**Results:**All tests were passed.

Biocompatibility evaluation and test

Biocompatibility evaluation conducted in accordance with the FDA's 2016 guidance and ISO10993-1:2018 supports that the subject devices are biocompatible.

The biocompatibility test includes the following tests:

- In vitro Cytotoxicity Test per ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.
- Skin Sensitization Tests per ISO 10993-10:2010 Biological evaluation of medical devices —Part 10: Tests for irritation and skin sensitization
- Skin Irritation Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization.

| Item | Proposed device | Result |
|---|---|---|
| Cytotoxicity | Under the conditions of the study, the device is noncytotoxic. | Pass |
| Irritation | Under the conditions of the study, the device is nonirritating. | Pass |
| Sensitization | Under the conditions of the study, the device is nonsensitizing | Pass |

**9. Summary of Clinical Performance Test**

No clinical study is included in this submission.

## 10. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Disposable Surgical Isolation Gown is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Surgical Isolation Gown(K203415).