February 23, 2023

StringKing
Thomas Frasca
Senior Partner
19100 S Vermont Avenue
Gardena, California 90248

Re: K221559
Trade/Device Name: Disposable Surgical Gown-Level 3
Disposable Surgical Gown-Level 4
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: January 20, 2023
Received: January 20, 2023

Dear Thomas Frasca:

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 -S

Bifeng Qian, M.D., Ph.D.
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)*
K221559

Device Name
Disposable Surgical Gown - Level 3
Disposable Surgical Gown - Level 4

Indications for Use *(Describe)*
The StringKing Surgical Gown is a sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids and particulate matter. The StringKing Surgical Gowns meet Level 3 and Level 4 requirements of ANSI/AAMI PB 70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

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.

K221559
510(k) SUMMARY

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

I. SUBMITTER

StringKing
19100 S. Vermont Avenue
Gardena, CA 90248
Tel: +1.508.654.1988
Fax: N/A

Contact Person: Tom Frasca
Date Prepared: February 23, 2023
Prepared by: Sharon Morrow, Regulatory Consultant

II. DEVICE

510(k):	K221559
Name of Device:	Disposable Surgical Gown, Level 4 Disposable Surgical Gown, Level 3
Classification Name:	Disposable Surgical Gown
Regulation:	21 CFR §878.4040
Regulatory Class:	Class II
Product Classification Code:	FYA

III. PREDICATE DEVICE

Predicate Manufacturer	B.J.ZH.F.PANTHER MEDICAL EQUIPMENT CO., LTD.
Predicate Trade Name:	Surgical Gown
Predicate 510(k):	K202706

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Disposable Surgical Gown consists of a multi-layer nonwoven spunbond-meltblown-spunbond (SMS) polyolefin & Film Lamination in the critical zones and a single layer of lighter, more breathable nonwoven SMS polyolefin in the non-critical zones. The StringKing Disposable Surgical Gown is designed for easy donning and doffing with hook and loop neck tabs, belt ties, removable transfer accessory, and polyester wrist cuffs. The StringKing Disposable Surgical Gown is one gown design that meets both Level 3 and Level 4 requirements of AMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. The gown will be marketed as a L3 gown as well as a L4 gown. The StringKing Disposable Surgical Gowns are single use, disposable medical devices that will be provided sterile.

V. INDICATIONS FOR USE

The StringKing Disposable Surgical Gown is a sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids and particulate matter. The StringKing Surgical Gowns meet Level 3 and Level 4 requirements of ANSI/AAMI PB 70:2012 *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

Device	Subject Device StringKing Disposable Isolation Gown (K221559)	Predicate: B.J.ZH.F. Panther Medical Equipment Co., Ltd. (K202706)	Justification for Differences
Manufacturer	StringKing	B.J.ZH.F. Panther Medical Equipment	N/A
510K Number	K221559	K202706	N/A
Product Common Name	Disposable Surgical Gown	Surgical Gown	Same
Product Code	FYA	FYA	Same
Classification	Class II (21 CFR 878.4040)	Class II (21 CFR 878.4040)	Same
Intended Use / Indications for Use	The StringKing Disposable Surgical Gown is a sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids and particulate matter. The StringKing Surgical Gowns meet Level 3 and Level 4 requirements of ANSI/AAMI PB 70:2012 *Liquid barrier performance and classification of protective apparel and drapes intended for use*	Surgical gowns are intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per *ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*, the surgical gowns met the requirements for Level 3 classification.	Intended Use is the Same. Subject Device also meets Level 4 requirements

	in health care facilities.		
Gown Sizes	Small, Medium, Large, X-Large, 2X-Large	Small, Medium, Large, X-Large, XX-Large and XXX-Large.	Similar; Predicate offers XXX-Large
Material Composition	SMS Reinforced SMS/PE – gown material and ties	SMS polypropylene nonwoven + Polyester	Similar;
Design Features	Neck Closure: Hook & Loop Tab Belt: Ties Cuffs: Knit Transfer Tab	Neck Closure: not included in 510k Summary. Belt: not listed in 510k Summary Cuffs: Knit	Similar
Color	Blue	Blue	Same
OTC Use	Yes	Yes	Same
Sterility	Sterile (EO)	Sterile (EO) and Bulk, non-sterile	Similar; predicates available bulk, non-sterile
Use	Single Use, Disposable	Single Use, Disposable	Same
ANSI/AAMI PB70	Level 3 and Level 4	Level 3	Same ; Subject Device also meets Level 4 requirements

Liquid Barrier Performance Classification Properties	Device was tested in accordance with AAMI PB70:2012 and meets Level 4 and Level 3 requirements 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 meet the requirements for Level 3 classification.	Same
Flammability	Meets requirements of Class 1 per 16 CFR 1610	Class 1 per 16 CFR 1610	Same
Non-barrier properties		Not specified in 510k summary	Same
Tensile Strength; ASTM D5034 (Machine Direction)	Meets requirements of ASTM D5034: ≥7lbf		
Tensile Strength; ASTM D5034 (Cross direction)	Meets requirements of ASTM D5034: ≥7lbf		
Trap Tear; ASTM D5587 (Machine Direction)	Meets requirements of ASTM D5587: ≥2.3lbf		
Trap Tear; ASTM D5587 (Cross Direction)	Meets requirements of ASTM D5587: ≥2.3lbf		
Seam Strength; ASTM D1683	Meets requirements of ASTM D1683: ≥7lbf		
Biocompatibility	Meets requirements of ISO 10993-5, ISO 10993-10, ISO 10993-23 (non-cytotoxic, non-irritant, non-sensitizer)	Meets requirements of ISO 10993-5, ISO 10993-10 (non-cytotoxic, non-irritant, non-sensitizer)	Same
Ethylene oxide residuals	Meets requirements of ISO 10993-7	Meets requirements of ISO 10993-7	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Test Standard	Acceptance Criteria	Results - Proposed Device – StringKing Disposable Surgical Gown (K221559)	Pass/Fail
ANSI/AAMI PB70:2012		Meets ANSI/AAMI PB 70:2012 Level 3 and Level 4 Liquid Barrier requirements	
Water Resistance Hydrostatic Pressure Test - AATCC 127:2017 (cm)	≥*50 cm*	All samples passed at ≥*50 cm*	Pass
Flammability of Clothing Textiles - 16 CFR Part 1610 (a)	Class 1: ≥3.5 seconds	All samples passed at ≥3.5 seconds	Pass
Durability ASTM D-5034	≥7lbf	All samples passed at greater than 7lbf	Pass
Tensile Strength ASTM D-5034 Machine Direction and Cross Direction	≥7lbf	All samples passed at greater than 7lbf	Pass

Trap Tear ASTM D5587-15 Machine Direction and Cross Direction	≥2.3lbf	All samples passed at ≥2.3lbf	Pass
Water Resistance Impact Penetration Test AATCC 42	≤1.0 g	All samples passed at ≤1.0g	Pass
ASTM D1683 Seam Strength	≥7lbf	All samples passed at ≥7lbf	Pass
ASTM F1671 Viral Penetration	Level 4: Blood and viral penetration resistance No penetration at 2psi	All samples showed no penetration at 2psi	Pass
Ethylene oxide residuals ISO 10993-7	EO <4mg* ECH <9mg	EO residuals were not detected ("ND")	Pass

*Daily dose

Sterilization & Shelf-life Testing

Sterilization validation according to ISO 11135; Shelf-life testing was conducted according to ASTM F1980-16 as well as ASTM F2096-11(2019) and ASTM F88/F88M-15.

Biocompatibility Testing

Biocompatibility Testing Endpoints	Acceptance Criteria	Results	Pass/Fail
Cytotoxicity – ISO 10993-5	≤Grade 2 (mild)	Grade 0	Pass

Skin Sensitization– ISO 10993-10	Primary Irritation Index 0-0.4 – Negligible 0.5-1.9-Slight 2-4.9-Moderate 5-8-Severe	0.0	Pass
Skin Irritation – ISO 10993-23	≤1 on Magnusson and Kligman Scale	0.0	Pass

Clinical testing: Clinical Studies are not required for this device and therefore are not included in this submission.

VIII. CONCLUSIONS

The conclusions drawn from the non-clinical tests demonstrate that the subject device in 510(k) submission K221559, the StringKing Surgical Gown is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K202706), manufactured by B.J.ZH.F. Panther Medical Equipment Co., Ltd.