December 8, 2017

GRI Medical & electrical Technology Co., Ltd
% Harry Shaffer
President
Sterilization Consulting Services, LLC
10051 Oak Leaf Way
Highlands Ranch, Colorado 80129

Re: K172445
Trade/Device Name: RoyalGuard Surgical Gown, i600, Breathable
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: November 3, 2017
Received: November 7, 2017

Dear Harry Shaffer:

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,

Tara A. 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)*

K172445

Device Name
RoyalGuard Surgical Gown, i600, Breathable

Indications for Use *(Describe)*

The RoyalGuard Surgical Gown, i600, Breathable is a single use surgical gown intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.

The RoyalGuard Surgical Gown, i600, Breathable has been tested and is classified as Level 4 in the critical zones per AAMI Standard PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare 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.

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SECTION C Summary

1 510(k) Summary

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

510(k) number:	K172445
Date:	Nov 3rd, 2017
Applicant:	GRI Medical & Electronic Technology Co., Ltd.
Contact:	Martin Paugh, V.P. of RA/QA 1805 HongGao Road XiuZhou Industry Zone JiaXing, ZheJiang, China, 314031 Tel: 86-135-1135-9722 Email: mpaugh@gri-china.com
Official Correspondent:	Harry Shaffer, President Sterilization Consulting Services LLC 10051 Oak Leaf way, Highlands Ranch, CO 80129 Tel: 303-929-3808 Email: HShaffer@Sterilizationconsulting.com
Device Trade Name:	RoyalGuard Surgical Gown, i600, Breathable
Common or Usual Name:	Surgical gown
Classification Name:	Surgical Apparel
Device Classification:	Class II per 21 CFR §878.4040 General and plastic surgery Product Code: FYA
Predicate Device: Reference Device	GRI ComfortGuard Surgical Gown, i600, Film Reinforced (K163191) Halyard Aero Chrome Breathable Performance Surgical Gown (K153255)

1.1 Description of the Device

The RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1) consists of a tri-laminate fabric Breathable Viral Barrier (BVB) including an outer and inner layer of spunbond polyolefin fabric with a middle layer of breathable monolithic film in the gown front body and gown sleeves. The gown sleeves critical zones also consist of an additional layer of Film Reinforcement Bi-laminate material, including a layer of spunbond and a layer of film. The gown back panels are comprised of a single layer of SMS (polyolefin nonwoven).

The RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1) is provided with neck binder, hook and loop tabs, belt ties, removable transfer accessory, and cuffs. There are eight regular sizes and two special sizes (A-frame) available for each design in both sterile and non-sterile packaging configurations, including: S, M, L, XL, XXL, L-XLONG, XL-XLONG, XXL-XLONG, A-frame L–XLONG, A-frame XL-XLONG. The two special sizes (A-frame L–XLONG, A-frame XL-XLONG) have much wider bottom that are designed for sitting procedures.

The RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1) has been tested according to AAMI PB70:2012 and met the AAMI Level 4 liquid barrier performance requirements. It is constructed with or without thumb-hooks in cuffs. The addition of thumb-hooks does not impact the performance of the gown in accordance with AAMI PB70 requirement.

1.2 Indications for Use

The RoyalGuard Surgical Gown, i600, Breathable is a single use surgical gown intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.

The RoyalGuard Surgical Gown, i600, Breathable has been tested and is classified as Level 4 in the critical zones per AAMI Standard PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.

1.3 Product Codes covered in this submission

Table 1 Product List

Product List		
Product Name	**Model Code without Thumb-hooks**	**Model Code with Thumb-hooks**
RoyalGuard Surgical Gown, i600, Breathable	i90-61xx-S1	i90-61xxT-S1
	i90-61xx	i90-61xxT

Table 2 Product Catalog Number and Description

Catalog #				Model Description	Size
Sterile		Non-Sterile			
Without Thumb-hook	**With Thumb-hook**	**Without Thumb-hook**	**With Thumb-hook**		
i90-6100-S1	i90-6100T-S1	i90-6100	i90-6100T	RoyalGuard Surgical Gown, i600, Breathable	S
i90-6110-S1	i90-6110T-S1	i90-6110	i90-6110T	RoyalGuard Surgical Gown, i600, Breathable	M
i90-6120-S1	i90-6120T-S1	i90-6120	i90-6120T	RoyalGuard Surgical Gown, i600, Breathable	L
i90-6130-S1	i90-6130T-S1	i90-6130	i90-6130T	RoyalGuard Surgical Gown, i600, Breathable	XL
i90-6140-S1	i90-6140T-S1	i90-6140	i90-6140T	RoyalGuard Surgical Gown, i600, Breathable	XXL
i90-6122-S1	i90-6122T-S1	i90-6122	i90-6122T	RoyalGuard Surgical Gown, i600, Breathable	L, XLONG
i90-6132-S1	i90-6132T-S1	i90-6132	i90-6132T	RoyalGuard Surgical Gown, i600, Breathable	XL, XLONG
i90-6142-S1	i90-6142T-S1	i90-6142	i90-6142T	RoyalGuard Surgical Gown, i600, Breathable	XXL, XLONG
i90-6124-S1	i90-6124T-S1	i90-6124	i90-6124T	RoyalGuard Surgical Gown, i600, Breathable	A-frame, L, XLONG
i90-6134-S1	i90-6134T-S1	i90-6134	i90-6134T	RoyalGuard Surgical Gown, i600, Breathable	A-frame, XL, XLONG

1.1 Summary of technological characteristics compared to the predicate

A comparison table for the proposed device, predicate device and reference device is provided in below table.

Table C 4 Comparison of Proposed Device, Predicate Device and Reference Device

General Information

Element of Comparison	Device Description	**Subject Device** **GRI RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1)**	**Predicate Device** **GRI ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)** **K163191**	**Reference Device** **Halyard Aero Chrome Breathable Performance Surgical Gown (4467x)** **K153255**
General	**Manufacturer**	GRI	GRI	Halyard
	Product Trade Name	RoyalGuard Surgical Gown, i600, Breathable	ComfortGuard Surgical Gown, i600, Film Reinforced	Aero Chrome Breathable Performance Surgical Gown
	Classification #	Class II, 21 CFR 878.4040	Class II, 21 CFR 878.4040	Class II, 21 CFR 878.4040
	Classification Name	Surgical Apparel	Surgical Apparel	Surgical Apparel
	Product Code	Surgical gown FYA	Surgical gown FYA	Surgical gown FYA
	AAMI PB 70 Classification	Level 4	Level 4	Level 4
	Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
	Comparison	Subject device is substantially equivalent to the predicate in classification and sterilization method.	**Predicate Device-** This device is a level 4 Film-Reinforced surgical gown per K163191 submission, and is used as the predicate.	**Reference Device** – this device is a level 4 surgical gown per K153255 submission, and is used as the reference device for “breathable” claim reference.

Indications for Use

Element of Comparison	Device Description	Subject Device GRI RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1)	Predicate Device GRI ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) K163191	Reference Device Halyard Aero Chrome Breathable Performance Surgical Gown (4467x) K153255
Indications for Use	**Indications for Use**	The RoyalGuard Surgical Gown, i600, Breathable is a single use surgical gown intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The RoyalGuard Surgical Gown, i600, Breathable has been tested and is classified as Level 4 in the critical zones per AAMI Standard PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.	The ComfortGuard Surgical Gown, i600, Film Reinforced is a single use surgical gown intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ComfortGuard Surgical Gown, i600, Film Reinforced has been tested and is classified as Level 4 in the critical zones per AAMI Standard PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.	The Aero Chrome* Breathable Performance Surgical Gowns are 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 Aero Chrome* Breathable Performance Surgical Gowns meet the Level 4 requirements of the AAMI PB70:2012 Liquid Barrier classifications. The Aero Chrome* Breathable Performance Surgical Gowns are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization.
	Comparison	Subject device is substantially equivalent to the predicate in its indications for use. The subject device and predicate are Level 4 surgical gowns.	**Predicate Device-** This device is a level 4 Film-Reinforced surgical gown per K163191 submission, and is used as the predicate.	**Reference Device** – this device is a level 4 surgical gown per K153255 submission, and is used as the reference device for “breathable” claim reference.

Technological Characteristics

Element of Comparison	Device Description	Subject Device GRI RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1)	Predicate Device GRI ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) K163191	Reference Device Halyard Aero Chrome Breathable Performance Surgical Gown (4467x) K153255
Technological Characteristics	Device Description	The RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1) consists of a tri-laminate fabric Breathable Viral Barrier (BVB) including an outer and inner layer of spunbond polyolefin fabric with a middle layer of breathable monolithic film in the gown front body and gown sleeves. The gown sleeves critical zones also consist of an additional layer of Film Reinforcement Bi-laminate material, including a layer of spunbond and a layer of film. The gown back panels are comprised of a single layer of SMS (polyolefin nonwoven). The RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1) is provided with neck binder, hook and loop tabs, belt ties, removable transfer accessory, and cuffs. The RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1) has been tested according to AAMI PB70:2012 and met the AAMI Level 4 liquid barrier performance requirements. It is constructed with or without thumb-hooks in cuffs. The addition of thumb-hooks does not impact the performance of the gown in accordance with AAMI PB70 requirement.	The ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) consists of a multi-layer in the critical zones (SMS & Film Lamination), single layer of SMS (polyolefin nonwoven) in the non-critical zones in the body and sleeve, single layer of SMS (polyolefin nonwoven) in the back panel with a lower basis weight SMS. The ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) is provided with neck binder, hook and loop tabs, belt ties, removable transfer accessory, and cuffs. The ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) has been tested according to AAMI PB70:2012 and met the AAMI Level 4 liquid barrier performance requirements. It is constructed with or without thumb-hooks in cuffs, with pleats in the back panels, with a lower basis weight SMS in the back panel. The addition of thumb-hooks, back pleats, and the use of a lighter basis weight material in the back panels does not impact the performance of the gown in accordance with AAMI PB70 requirement.	The Aero Chrome* Breathable Performance Surgical Gowns have a Spunbond/ Film/ Spunbond/ Meltblown/ Spunbond design (SFSMS) that provides AAMI Level 4 liquid barrier protection in the critical zones of the gown. The back of the Aero Chrome* Breathable Performance Surgical Gown in the non-critical zone has a SMS Spunbond/meltblown/spunbond) fabric that is air-breathable and provides AAMI Level 1 liquid barrier protection. The Aero Chrome* Breathable Performance Surgical Gowns are single use, disposable medical device that will be provided in a variety of sterile and non-sterile packaging configurations described below.

Continue on next page.

Technological Characteristics (cont.)

Element of Comparison	Device Description	Subject Device GRI RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1)	Predicate Device GRI ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) K163191	Reference Device Halyard Aero Chrome Breathable Performance Surgical Gown (4467x) K153255
Technological Characteristics (cont.)	Design Differences	The RoyalGuard Surgical Gown, i600, Breathable is constructed with a tri-laminate base material BVB in the gown front and sleeve, and the back is constructed with a single layer of SMS (polyolefin nonwoven).	The ComfortGuard Surgical Gown, i600, Film Reinforced is constructed with base material SMS throughout the entire gown.	The Aero Chrome* Breathable Performance Surgical Gowns have a Spunbond/ Film/ Spunbond/ Meltblown/ Spunbond design (SFSMS) that provides AAMI Level 4 liquid barrier protection in the critical zones of the gown. The back of the Aero Chrome* Breathable Performance Surgical Gown in the non-critical zone has a SMS Spunbond/meltblown/spunbond) fabric that is air-breathable and provides AAMI Level 1 liquid barrier protection.
		The RoyalGuard Surgical Gown, i600, Breathable has an additional film reinforcement layer in the sleeve critical zone. There is no reinforcement in the front body.	The ComfortGuard Surgical Gown, i600, Film Reinforced has another film reinforcement layer glued to the front and sleeve critical zones.	
	Predicate Comparison	With the construction and material difference to the predicate device, the barrier performance of the subject device is tested and met the AAMI Level 4 liquid barrier performance requirements and passed ISO 10993-1 biocompatibility requirements, and therefore the differences do not raise safety nor effectiveness concerns.	**Predicate-** This device is classified as a level 4 surgical gown in the critical zones per K163191 submission.	**Reference Device** – this device is a level 4 surgical gown per K153255 submission, and is used as the reference device for “breathable” claim reference.

Continue on next page.

Technological Characteristics (cont.)

Element of Comparison	Device Description	Subject Device GRI RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1)	Predicate Device GRI ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) K163191	Reference Device Halyard Aero Chrome Breathable Performance Surgical Gown (4467x) K153255
Technological Characteristics (cont.)	**Material Composition**	A tri-laminate fabric Breathable Viral Barrier (BVB) in the entire front and sleeve, additional Film reinforcement layer glued to the sleeve critical zones, single layer of SMS (polyolefin nonwoven) in back panels	Multi-layer in the critical zones (SMS & Film Lamination), single layer of SMS (polyolefin nonwoven) in the non-critical zones in the body and sleeve, single layer of SMS (polyolefin nonwoven) in the back panel with a lower basis weight SMS.	The Aero Chrome* Breathable Performance Surgical Gowns have a Spunbond/ Film/ Spunbond/ Meltblown/ Spunbond design (SFSMS) in the critical zones of the gown. The back of the Aero Chrome* Breathable Performance Surgical Gown in the non-critical zone has a SMS Spunbond/ meltblown/spunbond) fabric.
	Material Additives	Anti-Static throughout the entire gown	Alcohol-Repellency to Front Body and Sleeve materials Anti-Static throughout the entire gown	NA
	Predicate Comparison	With the exception of the material composition difference to the predicate device; The barrier performance of the subject device met the AAMI Level 4 liquid barrier performance requirements and passed ISO 10993-1 biocompatibility requirements, and therefore the differences do not raise safety nor effectiveness concerns.	**Predicate Device-** This device is classified as a level 4 surgical gown in the critical zones and passed ISO10993-1 biocompatibility requirements per K163191 submission.	**Reference Device** – this device is a level 4 surgical gown per K153255 submission, and is used as the reference device for “breathable” claim reference.

Safety Properties

Element of Comparison	Device Description	Subject Device GRI RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1)	Predicate Device GRI ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) K163191	Reference Device Halyard Aero Chrome Breathable Performance Surgical Gown (4467x) K153255
Safety Properties	**16 CFR Part 1610 (2014) Flammability**	Tested and met Class 1 requirement	Tested and met Class 1 requirement per K163191 submission	Tested and met Class 1 requirement per K153255 submission
	Biocompatibility	Testing was performed according to ISO 10993-5 and ISO 10993-10. Under the conditions of each study, the device is non-cytotoxic, non-sensitizing and non-irritating.	Testing was performed according to ISO 10993-5 and ISO 10993-10. Under the conditions of each study, the device is non-cytotoxic, non-sensitizing and non-irritating. per K163191 submission	Tested under ISO 10993 and passed. Under the conditions of the study, the device is non-cytotoxic, non-sensitizing and non-irritating. per K153255 submission
	Comparison	The RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1) is substantially equivalent to the predicate in safety properties in terms of Flammability and biocompatibility performance.	**Predicate Device –** This device meets Class 1 Flammability and Biocompatibility requirements per K163191 submission.	**Reference Device** – this device meets Class 1 Flammability and Biocompatibility requirements per K153255 submission.

Liquid Barrier Performance Classification Properties

Liquid Barrier Performance Classification Properties	Element of Comparison	Device Description	Subject Device GRI RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1)	Predicate Device GRI ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) K163191	Reference Device Halyard Aero Chrome Breathable Performance Surgical Gown (4467x) K153255
	Critical Zones	**AAMI PB70 ASTM F1671-13 Viral Penetration (Pass/Fail)** Level 4 requirement	All fabrics, seams and attachments in the critical zones passed ANSI/AAMI PB 70: 2012 Level 4 requirements	All fabrics, seams and attachments in the critical zones passed ANSI/AAMI PB 70: 2012 Level 4 requirements per K163191 submission	ANSI/AAMI PB70: 2012 Level 4 Liquid Barrier Requirements – Pass per K153255 submission.
	Non-Critical Zone (cont.)	**AAMI PB70 AATCC 42-2013 Impact Penetration (grams) Non-Critical Zone** Level 1 Requirements	All fabrics, seams and attachments in the non-critical zones passed ANSI/AAMI PB 70: 2012 Level 1 requirements	All fabrics, seams and attachments in the non-critical zones passed ANSI/AAMI PB 70: 2012 Level 1 requirements per K163191 submission	All fabrics, seams and attachments in the non-critical zones passed ANSI/AAMI PB 70: 2012 Level 1 requirements per K153255 submission.
	Comparison		The RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1) meets AAMI PB70 Level 4 requirements at critical zones and level 1 requirements at Non-Critical Zones and therefore is substantially equivalent to the predicate.	**Predicate Device** - The ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) meets AAMI PB70 Level 4 requirements at critical zones and meets PB70 level 1 requirements at Non-Critical Zones per K163191 submission.	**Reference Device** – this device meets ANSI/AAMI PB70: 2012 Level 4 Liquid Barrier Requirements in the critical zones and Level 1 requirement in the non-critical zones per K153255 submission.

Physical Properties

Element of Comparison	Device Description	Subject Device GRI RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1)	Predicate Device GRI ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) K163191	Reference Device Halyard Aero Chrome Breathable Performance Surgical Gown (4467x) K153255
Physical Properties (cont.)	**ASTM D3776 (2009) Basis Weight (gsm)** GRI Specifications	All fabrics passed internal specification requirements	All fabrics passed internal specification requirements per K163191 submission	NA
	ASTM D5034-09 (2013) Grab Tensile (Newton) GRI Specifications	All fabrics passed internal specification requirements	All fabrics passed internal specification requirements per K163191 submission	Fabrics in the critical zones passed specification requirements per K153255 submission
	ASTM D5587 (2015) Trapezoid Tear (Newton) GRI Specifications	All fabrics passed internal specification requirements	All fabrics passed internal specification requirements per K163191 submission	NA
	ASTM D1683 (2016) Seam Strength (Newton) GRI Specifications	All seams passed internal specification requirements	All seams passed internal specification requirements per K163191 submission	NA
	ASTM E96 (2016) WVTR GRI Specifications	The front material passed internal specification requirement	NA	Critical zone fabric utilized WSP 70.4 WVTR method and passed per K153255 submission
	Comparison	The RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1) meet the predetermined specifications for all physical properties.	**Predicate** - The ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) meet the predetermined specifications.	**Reference Device** – this device is used as the reference device for “breathable” claim.

1.2 Conclusion of the tests

Based on the results of the biocompatibility and physical performance testing, the GRI RoyalGuard Surgical Gown, i600, Breathable (i90-61xx-S1) is as safe and as effective, and as performs as well as the predicate device.