DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

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

February 27. 2017

Re: K163191
Trade/Device Name: Comfortguard Surgical Gown, i600, Film Reinforced
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: January 20, 2017
Received: February 6, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Susan Runner DDS, MA

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)*
K163191

Device Name
ComfortGuard Surgical Gown, i600, Film Reinforced

Indications for Use *(Describe)*
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.

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.

Date:	January 20th, 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:	ComfortGuard Surgical Gown, i600, Film Reinforced
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:	Kimberly-Clark ULTRA Film-Reinforced Surgical Gown(K080795)

1.1 Description of the Device

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. 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. And the reinforcement still covers the critical zone as in the other product codes.

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.

1.2 Indications for Use

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.

1.3 Product Codes covered in this submission

Table C 1 Product List

Product List		
Product Name	**Model Code without Thumb-hooks**	**Model Code with Thumb-hooks**
ComfortGuard Surgical Gown, i600, Film Reinforced	i90-82xx-S1	i90-82xxT-S1
	i90-82xx	i90-82xxT

Table C 2 Key for Surgical Gown Codes

Key for Surgical Gown Codes:	
Prefix	90= Surgical gown with Set-In sleeve
Suffix - 1	First position represents base “fabric" 8 = 47gsm SMS
Suffix - 2	Second position represents “reinforcement" 0 = None 2 = Film reinforcement
Suffix - 3(x)	Third position represents "size" 0 = Small 1 = Medium 2 = Large 3 = XL 4 = XXL
Suffix - 4(x)	Fourth position represents "length" 0 = Standard 2 = XLong 4 = A-frame
Suffix - 5	Fifth position represents "Thumb-hooks" T = with thumb-hooks
Suffix - 6	Sixth position represents "packaging" S1 = Sterile

Table C 3- Product Catalog Number and Description

Catalog #				Model Description	Size
Sterile		Non-Sterile			
Without Thumb-hook	With Thumb-hook	Without Thumb-hook	With Thumb-hook		
i90-8200-S1	i90-8200T-S1	i90-8200	i90-8200T	ComfortGuard Surgical Gown, i600, Film Reinforced	S
i90-8210-S1	i90-8210T-S1	i90-8210	i90-8210T	ComfortGuard Surgical Gown, i600, Film Reinforced	M
i90-8220-S1	i90-8220T-S1	i90-8220	i90-8220T	ComfortGuard Surgical Gown, i600, Film Reinforced	L
i90-8230-S1	i90-8230T-S1	i90-8230	i90-8230T	ComfortGuard Surgical Gown, i600, Film Reinforced	XL
i90-8240-S1	i90-8240T-S1	i90-8240	i90-8240T	ComfortGuard Surgical Gown, i600, Film Reinforced	XXL
i90-8222-S1	i90-8222T-S1	i90-8222	i90-8222T	ComfortGuard Surgical Gown, i600, Film Reinforced	L-XLONG
i90-8232-S1	i90-8232T-S1	i90-8232	i90-8232T	ComfortGuard Surgical Gown, i600, Film Reinforced	XL-XLONG
i90-8242-S1	i90-8242T-S1	i90-8242	i90-8242T	ComfortGuard Surgical Gown, i600, Film Reinforced	XXL-XLONG
i90-8224-S1	i90-8224T-S1	i90-8224	i90-8224T	ComfortGuard Surgical Gown, i600, Film Reinforced	A-frame, L-XLONG
i90-8234-S1	i90-8234T-S1	i90-8234	i90-8234T	ComfortGuard Surgical Gown, i600, Film Reinforced	A-frame, XL-XLONG

1.1 Summary of technological characteristics compared to the predicate

A side by side table between both proposed devices and predicate device is provided in below table.

Table C 4 Side by Side Comparison of Proposed Devices and Predicate Device

General Information

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown, code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown code 951xx (K080795)
General	**Manufacturer**	GRI	Kimberly-Clark Corp.	Kimberly-Clark Corp.
	Product Trade Name	ComfortGuard Surgical Gown, i600, Film Reinforced	ULTRA Film-Reinforced Surgical Gown	ULTRA 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 3
	Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
	Predicate Comparison	Subject device is substantially equivalent to the predicate in classification and sterilization method.	**Predicate-** This device is a level 4 Film-Reinforced surgical gown per K080795 submission, and is used as the predicate. The subject device is substantially equivalent to this gown for their indications for use.	This Device is a Level 3 non-reinforced surgical gown per K080795 submission. Subject device is not substantially equivalent to this gown. This gown is not considered as a predicate.

Indications for Use

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown, code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown, code 951xx (K080795)
Indications for Use	Indications for Use	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 Kimberly-Clark ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns are sterile, single use surgical gown intended to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.	The Kimberly-Clark ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns are sterile, single use surgical gown intended to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.
	Predicate 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**- This device is a level 4 Film-Reinforced surgical gown per K080795 submission, and is used as the predicate.	This Device is a Level 3 non-reinforced surgical gown per K080795 submission. Subject device is not substantially equivalent to this gown. This gown is not considered as a predicate.

Technological Characteristics

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown, code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown, code 951xx (K080795)
Technological Characteristics	Device Description	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.	Predicate Kimberly-Clark ULTRA Film-Reinforced Gown is a full-length, nonwoven SMS polypropylene gown. The ULTRA Film-Reinforced Surgical Gown is film-reinforced for higher barrier protection.	Kimberly-Clark ULTRA Gown is a full-length, nonwoven SMS polypropylene gown.
		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.	Predicate Kimberly-Clark ULTRA Film-Reinforced Gown is constructed with raglan sleeves, hook-and-loop neck closures, and tie waist closures.	Kimberly-Clark ULTRA Gown is constructed with raglan sleeves, hook-and-loop neck closures, and tie waist closures.

Continue on next page.

Technological Characteristics (cont.)

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown, code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown, code 951xx (K080795)
Technological Characteristics (cont.)	Design Differences	The ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) is constructed with or without thumb-hooks in cuffs.	Predicate Kimberly-Clark ULTRA Film-Reinforced Gown does not have thumb-hooks in cuffs.	Kimberly-Clark ULTRA Surgical Gown does not have thumb-hooks in cuffs.
		The ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) is constructed with pleats in the back panels.	Predicate Kimberly-Clark ULTRA Film-Reinforced Gown is not constructed with pleats in the back.	Kimberly-Clark ULTRA Surgical Gown is not constructed with pleats in the back.
	Predicate Comparison	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, and therefore is substantially equivalent to the predicate.	The predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown does not include these Design features	The Kimberly-Clark ULTRA Surgical Gown does not include these Design features

Continue on next page.

Technological Characteristics (cont.)

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown, code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown, code 951xx (K080795)
Technological Characteristics (cont.)	**Material Composition**	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.	Multi-layer construction (SMS & Film lamination) in the entire front body and sleeve, single layer of SMS (polyolefin nonwoven) in back panels	Single Layer of SMS (polyolefin nonwoven) throughout the entire gown
	Material Additives	Alcohol-Repellency to Front Body and Sleeves materials	Alcohol-Repellency throughout the entire gown.	Alcohol-Repellency throughout the entire gown.
		Anti-Static throughout the entire gown	Anti-Static throughout the entire gown	Anti-Static throughout the entire gown
	Predicate Comparison	The material compositions are same as the predicate. And the difference in material additives does not impact the performance of AAMI PB70 and ISO 10993-1 requirements, and therefore is substantially equivalent to the predicate.	The predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown meets the performance requirements of AAMI PB70 and ISO 10993-1 per K080795 submission.	The Kimberly-Clark ULTRA Surgical Gown meets the performance requirements of AAMI PB70 and ISO 10993-1 per K080795 submission.

Safety Properties

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown, code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown, code 951xx (K080795)
Safety Properties	**16 CFR Part 1610 (2014) Flammability**	Tested and met Class 1 requirement	Meets Class 1 requirement per K080795 submission	N/A
	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.	Passed ISO 10993-1 per K080795 submission	N/A
	Predicate Comparison	The ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) is substantially equivalent to the predicate in biocompatibility performance.	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown meets ISO 10993-1 per K080795 submission.	N/A

Liquid Barrier Performance Classification Properties- Critical Zones

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown, code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown, code 951xx (K080795)
Liquid Barrier Performance Classification Properties – Critical Zones	**AAMI PB70 ASTM F1671-13 Viral Penetration (Pass/Fail)** Test Results Pass/Fail (Results obtained from three independent Lots)	A1: Base Material: PASS	Meets ASTM F1671 Requirements per K080795 submission	N/A
		A2: Tie Attachment: PASS		
		B1: Lower Sleeve Seam: PASS		
		B2: Upper Sleeve Seam: PASS		
	AAMI PB70 ASTM F1671-13 Viral Penetration (Pass/Fail) Level 4 Requirements	A1: Base Material: Pass	Critical zone: Pass	N/A
		A2: Tie Attachment: Pass	Critical zone: Pass	
		B1: Lower Sleeve Seam: Pass	Critical zone: Pass	
		B2: Upper Sleeve Seam: Pass	Critical zone: Pass	
		AQL=4% (α=.05)	N/A	
		RQL=20% (β=0.10)	N/A	
		n=32; Acc=3; Rej=4	N/A	

Continue on next page.

Liquid Barrier Performance Classification Properties- Non-Critical Zone Front and Sleeve (cont.)

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown, code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown, code 951xx (K080795)
Liquid Barrier Performance Classification Properties- Non-Critical Zone (cont.)	**AATCC 42-2013 Impact Penetration (grams)** Test Results Mean (Min, Max) (Results obtained from Three Lots)	C1: Base Material: 0.03grams (0.00, 0.08)	N/A	N/A
		C2: Sleeve Joint Sewn Seam: 2.26grams (0.07, 4.42)		
		C3: Sleeve Seam: 0.00grams (0.00, 0.05)		
	AAMI PB70 AATCC 42-2013 Impact Penetration (grams) Level 1 Requirements	C1: Base Material: ≤4.5g	N/A	N/A
		C2: Sleeve Joint Sewn Seam: ≤4.5g		
		C3: Sleeve Seam: ≤4.5g		
		AQL=4% (α=.05)		
		RQL=20% (β=0.10)		
		n=32; Acc=3; Rej=4		
	Predicate Comparison	The ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) meets PB70 level 1 requirements at Non-Critical Zones.	N/A	N/A

Liquid Barrier Performance Classification Properties- Back (cont.)

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown, code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown, code 951xx (K080795)
Liquid Barrier Performance Classification Properties- Non-Critical Zone (cont.)	**AATCC 42-2013 Impact Penetration (grams)** Test Results Mean (Min, Max) (Results obtained from Three Lots)	D1: Back- Base Material: 1.00grams (0.07, 4.31)	N/A	N/A
		D2: Back Joint Sewn Seam: 2.54grams (0.21, 4.48)		
		D3: Back Tie Attachment: 0.89grams (0.00, 4.47)		
	AAMI PB70 AATCC 42-2013 Impact Penetration (grams) Level 1 Requirements	D1: Base Material: ≤4.5g		
		D2: Back Joint Sewn Seam: ≤4.5g		
		D3: Back Tie Attachment: ≤4.5g		
		AQL=4% (α=.05)		
		RQL=20% (β=0.10)		
		n=32; Acc=3; Rej=4		
	Predicate Comparison	The ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) meets PB70 level 1 requirements at Non-Critical Zones	N/A	N/A

Physical Properties

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown, code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown, code 951xx (K080795)
Physical Properties	**ASTM D3776 (2009) Basis Weight (gsm)** Test Results Mean (Min, Max) (Results obtained from Three Lots)	Critical zone - Body/Sleeve Material: 109.5gsm (103.0, 118.0)	N/A	N/A
		Non-Critical zone- Body/Sleeve Material: 49.3gsm (47.0, 52.0)		
		Back Material: 33.9gsm (32.0, 36.0)		
	ASTM D3776 (2009) Basis Weight (gsm) GRI Specifications	Critical zone - Body/Sleeve Material: Mean =102gsm (-10, +10)	N/A	N/A
		Non-Critical zone- Body/Sleeve Material: Mean =47gsm (-5, +5)		
		Back Material: Mean =33gsm (-3, +3)		

Continue on next page.

Physical Properties (cont.)

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown, code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown, code 951xx (K080795)
Physical Properties (cont.)	**ASTM D5034-09 (2013) Grab Tensile (Newton)** Test Result Mean (Min, Max) (Results obtained from Three Lots)	Critical Zone Body/Sleeve Material MD: 170.0N (151.6, 186.7)	N/A	N/A
		Critical Zone Body/Sleeve Material CD: 141.5N (115.4, 166.8)		
		Non-Critical Zone Body/Sleeve Material MD: 95.9N (85.2, 107.9)		
		Non-Critical Zone Body/Sleeve Material CD: 61.3N (53.4, 70.9)		
		Back Material MD: 82.6N (62.5, 101.5)		
		Back Material CD: 56.7N (43.1, 67.2)		
	ASTM D5034-09 (2013) Grab Tensile (Newton) GRI Specifications	Critical Zone Body/Sleeve Material MD: Mean MD ≥ 100N	N/A	N/A
		Critical Zone Body/Sleeve Material CD: Mean CD ≥ 70N		
		Non-Critical Zone Body/Sleeve Material MD: Mean MD ≥ 40N		
		Non-Critical Zone Body/Sleeve Material CD: Mean CD ≥ 20N		
		Back Material MD: Mean MD ≥ 40N		
		Back Material CD: Mean CD ≥ 20N		

Continue on next page.

Physical Properties (cont.)

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown, code 951xx (K080795)
Physical Properties (cont.)	**ASTM D5587 (2014) Trapezoid Tear (Newton)** Test Results Mean (Min, Max) (Results obtained from Three Lots)	Critical Zone Body/Sleeve Material MD: 57.3N (42.8, 73.2)	N/A	N/A
		Critical Zone Body/Sleeve Material CD: 75.0N (62.1, 88.3)		
		Non-Critical Zone Body/Sleeve Material MD: 16.5N (13.2, 21.4)		
		Non-Critical Zone Body/Sleeve Material CD: 25.4N (20.9, 34.9)		
		Back Material MD: 20.7N (14.4, 28.4)		
		Back Material CD: 33.3N (24.9, 46.1)		
	ASTM D5587 (2014) Trapezoid Tear (Newton) GRI Specifications	Critical Zone Body/Sleeve Material MD: Mean MD ≥ 20N	N/A	N/A
		Critical Zone Body/Sleeve Material CD: Mean CD ≥ 40N		
		Non-Critical Zone Body/Sleeve Material MD: Mean MD ≥ 10N		
		Non-Critical Zone Body/Sleeve Material CD: Mean CD ≥ 20N		
		Back Material MD: Mean MD ≥ 10N		
		Back Material CD: Mean CD ≥ 20N		

Continue on next page.

Physical Properties (cont.)

Element of Comparison	Device Description	ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1)	Predicate Kimberly-Clark ULTRA Film-Reinforced Surgical Gown, code 954xx, 955xx (K080795)	Kimberly-Clark ULTRA Surgical Gown, code 951xx (K080795)
Physical Properties (cont.)	**ASTM D1683 (2007) Seam Strength (Newton)** Test Results Mean (Min, Max) (Results obtained from Three Lots)	Outer Sleeve Seam: 47.4N (21.0, 60.2)	N/A	N/A
		Inner Sleeve Seam: 90.4N (75.2, 106.0)		
	ASTM D1683 (2007) Seam Strength (Newton) GRI Specifications	Outer Sleeve seam: Min ≥20N	N/A	N/A
		Inner Sleeve seam: Min ≥50N		
	Predicate Comparison	The ComfortGuard Surgical Gown, i600, Film Reinforced (i90-82xx-S1) meet the predetermined specifications.	N/A	N/A

1.2 Conclusion of the tests

Based on the results of the biocompatibility and physical performance testing, the GRI ComfortGuard Surgical Gown, i600, Film Reinforced is as safe and as effective, and as performs as well as the predicate device for its indications for use. The ComfortGuard Surgical Gown, i600, Film Reinforced is substantially equivalent to the predicate device.