K102652

gri

§5. 510(k) Summary

FEB - 3 2011

5.1 Submitted by: GRI MEDICAL & ELECTRONIC TECHNOLOGY CO., LTD.
1805 HongGao Road, XiuZhou Industry Zone, ZheJiang,
China, 314031
86-573-83916501
86-573-83916520

5.2 Contact Person: Penny Northcutt
REGSolutions, LLC.
717 Lakeglen Drive
Suwanee, GA 30024
Fax: (678) 513-0937
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Email: pennynorthcutt@theregsolutions.com

5.3 Summary Date: December 1, 2010

5.4 Device Name: Gowns Surgical
5.5 Common/Usual Name: Surgical gown
5.6 Device Classification: General & Plastic Surgery
Class II - 21 CFR 878.4040
5.7 Device Product Code: FYA

5.8 Device Description:

GRI's Non Reinforced, Film Reinforced and Fabric Reinforced Surgical Gowns are made from SMS fabrics and polypropylene/polyethylene protective reinforcement to provide user protection in surgical settings. The gowns are available in various designs and combinations of materials, sizes, and reinforcement configurations.

The Non Reinforced Surgical Gowns meet the requirements of AAMI Level 2 liquid barrier requirements.

The Fabric-Reinforced Surgical Gowns meet the requirements of AAMI Level 3 liquid barrier requirements.

The Film-Reinforced Surgical Gowns meet the requirements of AAMI Level 3 liquid barrier requirements.

5.9 Predicate Device Information and Substantial Equivalence:

GRI Gowns	Predicate Gowns
Group 1 – Non Reinforced Surgical Gowns Product codes 90-10XX-S and 90-20XX-S	Kimberly Clark K093115 KC 100 Surgical Gowns Product code 99284, 99285, 99294, 99295
GRI Gowns Group 2 Film Reinforced Surgical Gowns Product codes 90-12XX-S and 90-22XX-S	Astound by Convertors K061308 Impervious Film Reinforced Surgical Gowns, Product code Cat. 9040
GRI Gowns Group 3 Fabric Reinforced Surgical Gowns Product codes 90-13XX-S and 90-24XX-S	Kimberly Clark K080795 Fabric Reinforced Surgical Gowns Product code 95211

GRI's Non Reinforced, Film Reinforced and Fabric Reinforced gowns are substantially equivalent to the above predicates in intended use statements, equivalent device construction, materials, gown design, and technology performance characteristics.

5.10 Indications for Use:
GRI's Non Reinforced, Film Reinforced, and Fabric Reinforced Surgical Gowns are sterile or non-sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.

5.11 Summary of Testing:
GRI Surgical Gowns have met acceptance criteria for bench testing including biocompatibility, hydrostatic pressure, impact penetration, Resistance to Penetration by Synthetic Blood, linting, flammability, and strength via tensile, tear and seam strength.

5.12 Conclusion:
Based on the performance testing and device attributes, it can be concluded that the GRI surgical gowns are equivalent to the predicate devices with respect to the indications for use and technological characteristics and do not present any further safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

GRI Medical & Electronic Technology Company, Limited
C/O Ms. Penny Northcutt
Regsolutions, LLC
717 Lakeglen Drive
Suwanee, Georgia 30024

FEB - 3 2011

Re: K102652
Trade/Device Name: Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: January 19, 2011
Received: January 20, 2011

Dear Ms. Northcutt:

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.

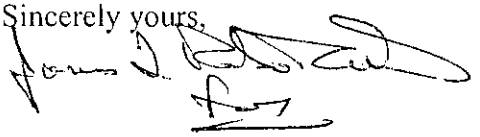
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use: Sterile products

510(k) Number (if known): K102652

Device Name: Surgical Gowns

GRI's Non Reinforced Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. GRI's Non Reinforced Surgical Gowns meet Level 2 of the AAMI Liquid Barrier classifications. See Page 4-2 for product list.

GRI's Film Reinforced Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. GRI's Film Reinforced Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications. See Page 4-2 for product list.

GRI's Fabric Reinforced Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. GRI's Fabric Reinforced Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications. See Page 4-2 for product list.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Mansfield-Wells

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K102652

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Indications for Use Product List: Sterile

Product Name	Model Code	Primary Material
GRI Non-Reinforced Surgical gown	90-10XX-S	50gsm SMS in blue, Non-reinforced
	90-20XX-S	35gsm SMS in blue, Non-reinforced
GRI Film-Reinforced Surgical gown	90-12XX-S	50gsm SMS in blue with film reinforcement
	90-22XX-S	35gsm SMS in blue with film reinforcement
GRI Fabric-Reinforced Surgical gown	90-13XX-S	50gsm SMS in blue with 50gsm SMS reinforcement
	90-24XX-S	35gsm SMS in blue with 35gsm SMS reinforcement

Key for Surgical Gown Codes:

Prefix	90= Surgical gown series
Suffix - 1	First position represents "fabric"
	1 = 50gsm SMS
	2 = 35gsm SMS
Suffix - 2	Second position represents "reinforcement"
	0 = None
	2 = Film reinforced
	3 = Fabric, 50gsm SMS
	4 = Fabric, 35gsm SMS
Suffix - 3(x)	Third position represents "size"
	0 = Small
	1 = Medium
	2 = Large
	3 = Xlarge
	4 = XXLarge
Suffix - 4(x)	Fourth position represents "length"
	0 = Standard
	1 = XLong
Suffix - 5	Fifth position represents "packaging"
	S = Sterile

Indications for Use: Non-Sterile products

510(k) Number (if known): K102652

Device Name: Surgical Gowns

GRI's Non Reinforced Surgical Gowns are non-sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. GRI's Non Reinforced Surgical Gowns meet Level 2 of the AAMI Liquid Barrier classifications. See Page 4-4 for product list.

GRI's Film Reinforced Surgical Gowns are non-sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. GRI's Film Reinforced Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications. See Page 4-4 for product list.

GRI's Fabric Reinforced Surgical Gowns are non-sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. GRI's Fabric Reinforced Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications. See Page 4-4 for product list.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 4-3 of 4-4

Elizabeth F. Claus-Wells

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102652

Indications for Use Product List: Non-Sterile

Product Name	Model Code	Primary Material
GRI Non-Reinforced Surgical gown	90-10XX	50gsm SMS in blue, Non-reinforced
	90-20XX	35gsm SMS in blue, Non-reinforced
GRI Film-Reinforced Surgical gown	90-12XX	50gsm SMS in blue with film reinforcement
	90-22XX	35gsm SMS in blue with film reinforcement
GRI Fabric-Reinforced Surgical gown	90-13XX	50gsm SMS in blue with 50gsm SMS reinforcement
	90-24XX	35gsm SMS in blue with 35gsm SMS reinforcement

Key for Surgical Gown Codes:

Prefix	90= Surgical gown series
Suffix - 1	First position represents "fabric"
	1 = 50gsm SMS
	2 = 35gsm SMS
Suffix - 2	Second position represents "reinforcement"
	0 = None
	2 = Film reinforced
	3 = Fabric, 50gsm SMS
	4 = Fabric, 35gsm SMS
Suffix - 3(x)	Third position represents "size"
	0 = Small
	1 = Medium
	2 = Large
	3 = Xlarge
	4 = XXLarge
Suffix - 4(x)	Fourth position represents "length"
	0 = Standard
	1 = XLong