EMM
Exact Medical Manufacturing, Inc.

JUN 1 2 2012

Sec. 6: 510(k) Summary – EMM Surgical Gown with AAMI Liquid Barrier Level IV K120045

Date Summary was Prepared	December 31, 2011
510(k) Submitter	David Nowicki, President Exact Medical Manufacturing Inc. 4917 William Street, Suite C Lancaster, NY 14086 dnowicki@exactmm.com (p)716-681-0866, (f) 716-681-4110
Primary Contact for this 510(k) Submission	David Nowicki, President Exact Medical Manufacturing Inc. 4917 William Street, Suite C Lancaster, NY 14086 dnowicki@exactmm.com (p)716-681-0866, (f) 716-681-4110
Device Common Name	Surgical Gown
Trade Name	Surgical Gown with AAMI Liquid Barrier Level IV
Device Product Codes and Classification Name	FYA, 21CFR878.4040, Surgical Apparel
Predicate Device	Convertors SmartGown K992514
Device Description	Exact Medical Manufacturing Surgical Gown with AAMI Liquid Barrier Level IV are sterile or non-sterile single use devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Exact Medical Manufacturing Surgical Gown with AAMI Liquid Barrier Level IV is comprised of a 3 ply laminate non woven material - outer layers are nonwoven fabric - inner layer AAMI PB:70 Level 4 capable film. The gowns consist of 100% polyester cuffs sewn to the end of the sleeves using nylon thread. The gowns have a manual closure system.
Intended Use	Exact Medical Manufacturing Surgical Gown with AAMI Liquid Barrier Level IV are sterile or non-sterile single use devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The Exact Medical Manufacturing Surgical Gown with AAMI Liquid Barrier Level IV are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization.
Technological Characteristics	Exact Medical Manufacturing Surgical Gown with AAMI Liquid Barrier Level IV has the same design, material and performance characteristics of the predicate device.
Summary of Testing	Exact Medical Manufacturing Surgical Gown with AAMI Liquid Barrier Level IV is substantially equivalent and meets the same acceptance criteria as the predicate device/gown in K992514 Non-clinical performance testing includes: Biocompatibility (cytotoxicity, irritation, sensitization) in compliance with the methods of ISO 10993, Barrier properties- AAMI PB:70 Level 4, tensile, tear strength, flammability, linting and sterility. All results of the testing met acceptance criteria.
Substantial Equivalence	The surgical gowns described in this 510(k) submission are substantially equivalent in all specifications and performance compared to the predicate device indentified in K992514.

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

Mr. David Nowicki
President
Exact Medical Manufacturing, Incorporated
4917 William Street, Suite C
Lancaster, New York 14086

JUN 12 2012

Re: K120045
Trade/Device Name: Exact Medical Manufacturing Surgical Gown with AAMI Level IV Liquid Barrier, Model # 19-121, Sizes L, XL, XXL, XLXL
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: June 1, 2012
Received: June 4, 2012

Dear Mr. Nowicki:

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.

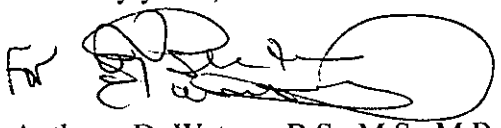
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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:

510(k) Number (if known): K120045

Device Name: Exact Medical Manufacturing Surgical Gown with AAMI Level IV Liquid Barrier, Model # 19-121, Sizes L, XL, XXL, XLXL

Indications for Use: Exact Medical Manufacturing Surgical Gown with AAMI Liquid Barrier Level IV are sterile or non-sterile single use devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Sterile surgical gowns are to be sold directly to users after EtO sterilization and validated to ISO 11135-1:2007.

The Exact Medical Manufacturing Surgical Gowns with AAMI Level IV Liquid Barrier are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization according to ISO 11135-1:2007

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)

Elizabeth F. Claverie-Wilson

)ivision Sign-Off)
:vision of Anesthesiology, General Hospital
'ection Control, Dental Devices

,10(k) Number: K120045