July 13, 2018

GMAX Industries, Inc.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.Box 120-119
Shanghai, 200120 Cn

Re: K172987
Trade/Device Name: Surgical Gown (AE1001, AE2001, AE3001)
Surgical Gown (AG1001, AG2001, AG3001)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: June 20, 2018
Received: June 22, 2018

Dear Diana Hong:

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 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,

Elizabeth F. Claverie -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172987

Device Name
Surgical Gown (AE1001, AE2001, AE3001)

Indications for Use *(Describe)*
Surgical gown is 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 AE series surgical gowns met the requirements for Level 2 classification.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172987

Device Name
Surgical Gown (AG1001, AG2001, AG3001)

Indications for Use *(Describe)*
Surgical gown is 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 AG series surgical gowns met the requirements for Level 3 classification.

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K172987

1. Date of Preparation: 7/12/2018

2. Sponsor Identification

GMAX Industries, Inc.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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P.O. Box 120-119, Shanghai, 200120, China

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Email: info@mid-link.net

4. Identification of Subject Device

Trade Name:
Surgical Gown (AE1001, AE2001, AE3001);
Surgical Gown (AG1001, AG2001, AG3001)
Common Name: Gown, Surgical

Regulatory Information
Classification Name: Gown, Surgical
Classification: II
Product Code: FYA
Regulation Number: 21 CFR 878.4040
Review Panel: General& Plastic Surgery

Indications for Use for AE series:
Surgical gown is 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 AE series surgical gowns met the requirements for Level 2 classification.

Indications for Use for AG series:
Surgical gown is 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 AG series surgical gowns met the requirements for Level 3 classification.

Device Description
The Surgical Gown is a single use, disposable medical device provided as bulk, non-sterile items to repackagers/ relabler for further packaging and Ethylene Oxide (EO) sterilization.

The subject device includes six models, which are provided in Table 1 Model List. The six models have the same product size, the only difference is whether the surgical gown has an inside reinforcement and material of the reinforcement. AG1001 and AE1001 don’t have the reinforcement. AG2001 and AE2001 have an inside trapezoidal fabric-reinforcement on the chest and two sleeves of the gown. AG3001 and

AE3001 have an inside rectangular poly-reinforcement on the chest and two sleeves of the gown.

Table 1 Model List

Model	Size	Style	AAMI level
AG1001	XL	Non-reinforced	3
AG2001	XL	Fabric-reinforced	3
AG3001	XL	Poly-reinforced	3
AE1001	XL	Non-reinforced	2
AE2001	XL	Fabric-reinforced	2
AE3001	XL	Poly-reinforced	2

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K043585
Product Name: Medline Eclipse™ Surgical Gown
Manufacturer: MEDLINE INDUSTRIES, INC.

Predicate Device 2
510(k) Number: K120192
Product Name: Disposable Surgical Gowns
Manufacturer: Weihai Hongyu Nonwoven Fabric Products Co., Ltd.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

- ASTM D737-04 (2016) Standards Test Method for Air Permeability of Textile Fabrics
- 16 CFR 1610: 2008 Standard for the Flammability of Clothing Textiles
- AATCC 127:2003 Water Resistance: Hydrostatic Pressure Test
- AATCC 42:2007 Water Resistance: Impact Penetration Test
- ISO 9073-10:2003 Textiles- Test Method for Nonwovens- Part 10: Lint and Other Particles Generation in the Dry State
- ASTM D1683-11 Standard Test Method for Failure in Sewn Seams of Woven Apparel Fabrics
- ASTM D5587-15 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
- ASTM D5034-09 (2017) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
- ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests for in vitro

Cytotoxicity

- ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 2 Comparison of Technology Characteristics

Item	Subject Device	Predicate Device 1 K043585	Predicate Device 2 K120192	SE Assessment
Product Code	FYA	FYA	FYA	Same
Regulation Number	878.4040	878.4040	878.4040	Same
Indications for Use	Surgical gown is 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 AE series surgical gowns met the requirements for Level 2 classification, the AG series surgical gowns met the requirements for Level 3 classification.	Medline Disposable EclipseTM Surgical Gowns are surgical apparel 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 body fluids, micro-organisms, and particulate material.	Disposable Surgical Gowns, which are blue colored and EO sterilized, are indicated 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. It culd achieve Level 3 Barrier Performance as per AAMI PB70:2003. It is for single use only.	Similar

Style		Non-reinforced/ Fabric-reinforced/ Poly-reinforced	Non-reinforced/ Fabric-reinforced/ Poly-reinforced	Reinforced	Same
Size		XL	L, XL,XXL	M, L, XL, XXL	See note below Difference 1
Physical specification	Barrier protection level	Level 2/Level 3 per AAMI PB70	Level 2 per AAMI PB70	Level 3 per AAMI PB70	Same
	Tearing strength	>30N	Not known	Not known	See note below Difference 2
	Fire protection	Class I	Not known	Class I	Same
	Lint:	Log_{10}< 4	Not known	Not known	See note below Difference 3
	Air Permeability	>30 ft3/min/ft2	Not known	Not known	
Mechanical specifications	Tensile strength	≥20N	Not known	≥20N	Same
	Durability	Disposable	Disposable	Disposable	Same
Material		SMMMS, Polypropylene, PE (Poly Ethylene), Polyester	SMS	SMS, SPP, Polypropylene, PE, Nylon, Polyester	See note below Difference 4
Biocompatibility		Under the conditions of the study, the device is non-toxic,	Under the conditions of the study, the device is non-toxic,	Under the conditions of the study, the device is non-toxic,	Same

	non-irritating, and non-sensitizing.	non-irritating, and non-sensitizing.	non-irritating, and non-sensitizing.	

Difference 1

The subject devices only have one size of XL, while the predicate device 1 has three kinds of sizes which are L, XL, XXL, and the predicate device 2 has four kinds of device which are M, L, XL, XXL. The difference in the size will not affect the function. So the difference in the size will not affect the safety and effectiveness of the subject device.

Difference 2

Although the tearing strength of the predicate devices are unknown, the tearing strength of the subject device is large enough for safety using. Therefore this different will not raise new safety and effectiveness questions.

Difference 3

Although the linting level of the predicate devices are unknown, the linting level of the subject device is acceptable for safety using. Therefore this different will not raise new safety and effectiveness questions.

Difference 4

The main material of the subject device is SMMMS, and the main material of the Predicate Device 1 and Predicate Device 2 is SMS, the difference between the material of the subject device and predicate devices is the amounts of the meltblown layers. Therefore, this difference will not affect the substantially equivalency of the subject device.

9. Conclusion

Based on the results of the nonclinical testing, the Surgical Gowns are as safe and as effective, and as performs as well as the K043585 and K120192 predicate device.