July 30, 2021

Advanced Medical Design Co., Ltd.
Mr. Jose Wang
Regulatory Affair
4-5F, No 29, Wuquan 5th Rd., Wugu Dist.
New Taipei City, 248
Taiwan, R.O.C.

Re: K210248
Trade/Device Name: Lab Bag with Fabric Pouch
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 6, 2021
Received: June 9, 2021

Dear Mr. Wang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210248

Device Name
Lap Bag with Fabric Pouch

Indications for Use *(Describe)*
The Lap Bag with fabric pouch system is applied in minimally invasive abdominal procedures for the safe and convenient removal of the tissue, organ or specimen during surgery.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Company Name: **Advanced Medical Design Co., Ltd.**
Phone: +886-2-2290-2627
Fax: +886-2-2298-1789
Contact Person: Mr. Jose Wang
Regulatory Affair Specialist
Phone: +886-2-2290-2627 Ext. 511
E-mail: jose.wang@amdintl.com.tw
Mailing Address: 4F~5F, No29, Wuquan 5th Rd., Wugu Dist., New Taipei city, 248 Taiwan R.O.C.
Date Prepared: July. 28, 2021

II. DEVICE INFORMATION

Name of Device: Lap Bag with Fabric Pouch
Device Classification Name: Laparoscope, General & Plastic Surgery
Regulation Number: 21 CFR 876.1500
Regulatory Class: II
Product Code: GCJ

III. PREDICATE DEVICE

Trade/Device Name	Laparoscopic Tissue Retrieval Bag, Model 24003-MF
510(k) Number	K123728
Product Code	GCJ
Submitter	FLEXBAR MACHINE CORP.

IV. DEVICE DESCRIPTION

The Lap Bag with fabric pouch is applied in minimally invasive abdominal procedures for the safe and convenient removal of tissue, organ or specimens during surgery.

The device is a TPU and nylon bonded fabric pouch that minimizes spillage and intraoperative contamination by isolating and containing tissue specimens. It is designed for introduction and use through 11/12 and 15mm cannula.

The product is a single-use, sterile, and biocompatible laparoscopic accessory device. It is packaged by the Tyvek® 1073B sterile pouch and its shelf life is 3 years.

V. INDICATIONS FOR USE

The Lap Bag with fabric pouch system is applied in minimally invasive abdominal procedures for the safe and convenient removal of tissue, organ or specimens during surgery.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The substantial equivalent comparison table was summarized in Table 5.1.

Table 5.1. The Substantial Equivalent Comparison Table

Device Name	Subject Device	Predicate Device
	Lap Bag with Fabric Pouch	**Laparoscopic Tissue Retrieval Bag, Model 24003-MF**
510(k) Number	TBD	K123728
510(k) Submitter	Advanced Medical Design Co., Ltd.	FLEXBAR MACHINE CORP.
Indications for Use and Intended Use	The Lap Bag with fabric pouch system is applied in minimally invasive abdominal procedures for the safe and convenient removal of the tissue, organ or specimen during surgery.	The Mediflex device is a laparoscopic tissue retrieval bag model 24003-MF. The sterile bag is a single use disposable device used as a receptacle for collection and extraction of tissue during laparoscopic surgical procedures.
Product Code	GCJ	GCJ
Prescription / over-the counter use	Prescription use	Prescription use
Reusable / Disposable	Single use	Single use
Function	To isolate and contain tissue specimens.	Collection, extraction of tissue via 10 mm, 11 mm or 12 mm cannula
Compatibility with Other Devices	11/12 and 15mm cannula	10 mm, 11 mm or 12 mm cannula
Biocompatibility	ISO 10993-1	ISO 10993-1
Sterile Barrier	Tyvek® Pouch	Tyvek® Pouch
Sterilization Method	ISO 11135-1 EO method (SAL: 10^{-6})	ISO 11135-1 EO method (SAL: 10^{-6})
Bag Material	TPU and Nylon	PU coated on nylon polyamide
Open / Close Method	Instruction Section 13	Instruction
Durability / Shelf Life	ISO 11607 / 3 years shelf	ISO 11607 / 5 years shelf
Nature of body contact / Duration	Tissue, Blood / <24 hr	Tissue, Blood / <24 hr

Through the substantially equivalent comparison table, the differences do not raise any different issues on the safety or effectiveness of the product.

VII. PERFORMANCE DATA

A series of the studies were performed to evaluate the safety and effectiveness of Lap Bag with Fabric Pouch. The following test results were provided to confirm the product is safe and effective as

indicated.

A. Biocompatibility Testing

The biocompatibility test was evaluated per the FDA recognized consensus standard named “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on June 16, 2016, the biocompatibility tests include the following items since the product is classified as the classification.

Nature of Body Contact		Contact Duration
Category	Contact	
External communicating device	Tissue/bone/dentin	Limited (≦24 h)

No.	Test Name	Applicable Standards	Comment
1	Cytotoxicity Test	ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Pass
2	Sensitization Test	ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Pass
3	Intracutaneous reactivity Test	ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Pass
4	Acute Systemic Toxicity Test	ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Pass
5	Material-Mediated Pyrogenicity Test	USP <151> Pyrogen Test	Pass

All of the test studies listed above showed that Lap Bag with Fabric Pouch did not raise any safety issues and is biocompatible.

B. Sterilization Validation and Shelf Life Study

The product is designed to perform Ethylene oxide sterilization prior to place into the market, therefore the following studies should be evaluated by the applicable standards/guidance.

a. Ethylene oxide Sterilization Validation Study

The Ethylene oxide sterilization validation study was performed per the requirements of the FDA recognized consensus standards listed below.

-ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

-ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product

-ISO 11737-2:2019 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

The product is sterilized using established E.O. sterilization by Sterilize Service Corporation. Using "Over Kill Half Cycle" based on ISO 11135:2014 to verify whether Lap Bag with Fabric Pouch meets the requirements of SAL 10^{-6}.

b. Product Aging Validation Study (Shelf Life Study)

The product aging validation study was performed for 3 years per the FDA recognized consensus standards "ISO 11607-1:2019 Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems" to determine the shelf life of the product, since the product is supplied in the sterile status.

The Aging Validation Study included the following test studies.
Since the shelf life of the product is proposed to be stored for 3 years, the aging validation study is performed which included the following test items.

No.	Test Name	Applicable Standards	Comment
1	Package Integrity Test (Dye penetration Test)	ASTM F1929-15:2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Pass
2	Seal Peel Strength Test	ASTM F88/F88M-15:2015 Standard Test Method for Seal Strength of Flexible Barrier Materials	Pass
3	Product Sterility Test	ISO 11737-2:2019 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	Pass

All of the aging test data showed that the product can be safe and effective during its predetermined shelf life. Hence, the sterile assurance level and the functional specification of the product meet the firm's definition and regulatory requirement, the shelf life of the product is 3 years.

C. Product Performance Test

Performance Bench testing was performed to verify the performance to specifications of the proposed device and included the following:

No.	Test Name	Applicable Standards	Comment
1	loading capacity test	N/A (followed by the internal testing protocol)	Pass
2	leak-resistant test	N/A (followed by the internal testing protocol)	Pass

All of the test data showed that the Loading capacity test and Leakage-resistant function of all Lap Bag with Fabric Pouch meet the requirement.

VIII. Conclusion

The Lap Bag with Fabric Pouch has the same technological characteristics and intended uses as the predicate 24003-MF (K123728); and

The labeling of the Lap Bag with Fabric Pouch is concordant with the predicate device and FDA requirements; and

The information submitted to the FDA for the Lap Bag with Fabric Pouch does not raise new questions about safety or effectiveness and demonstrates with reasonable assurance based on established controls that the device is at least as safe and effective as a legally marketed device.

Therefore, the Lap Bag with Fabric Pouch is substantially equivalent to the predicate device.