July 10, 2020

Beijing Biosis Healing Biological Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K201243
Trade/Device Name: Disposable Specimen Retrieval Bag
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 22, 2020
Received: May 8, 2020

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. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201243

Device Name
Disposable Specimen Retrieval Bag

Indications for Use *(Describe)*
The device is indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic procedures.

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.

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Tab #6 510(k) Summary

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

The assigned 510(k) Number: _____

1. Date of Preparation: 04/22/2020

2. Sponsor Identification

Beijing Biosis Healing Biological Technology Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Disposable Specimen Retrieval Bag
Common Name: Specimen Retrieval Bag
Models: RJRB-50, RJRB-100, RJRB-120, RJRB-150, RJRN-200, RJRB-250, RJRB-300, RJRB-320, RJRB-350, RJRB-420

Regulatory Information

Classification Name: Laparoscope, General& Plastic Surgery;
Classification: II;
Product Code: GCJ;
Regulation Number: 21CFR 876.1500
Review Panel: General & Plastic Surgery;

Indication for Use:
The device is indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic procedures.

Device Description

The proposed device, Specimen Retrieval Bag, is comprised of retracted bag, steel sheet, plug, inner sleeve, outer sleeve, pull ring, outer introducer handle, joint, tightening line, pick rod and inner introducer handle. The device is available in a series of models: RJRB-50, RJRB-100, RJRB-120, RJRB-150, RJRN-200, RJRB-250, RJRB-300, RJRB-320, RJRB-350, RJRB-420. The difference between each model is the retracted bag size and volume. The device is provided sterile and single use

5. Identification of Predicate Device

510(k) Number: K172789
Product Name: Specimen Retrieval Bag

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

The performance tests were performed on both proposed device and predicate device. The test items include follow items

- Retracted Bag Peeling Force Test

- Tightening Line Tensile Strength Test
- Force to Push out Retracted Bag Test
- Force to Withdraw Retracted Bag Test
- Penetration Force Test
- Leak Test

Sterile Barrier Packaging Testing performed on the proposed device:

- Visual Inspection
- Seal strength
- Dye penetration

Sterilization and Shelf Life Testing performed on the proposed device:

- EO residue
- ECH residue
- Shelf Life Evaluation

Biocompatibility testing

The biocompatibility evaluation for the proposed device was conducted in accordance with the FDA guidance document "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process'" June, 2016, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The proposed device was evaluated for the following tests:

- Cytotoxicity,
- Sensitization,
- Intracutaneous reactivity,
- Systemic Toxicity,
- Pyrogen

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K172789
Product Code	GCJ	GCJ
Regulation No.	21 CFR 880.5860	21 CFR 880.5860
Class	Class II	Class II
Indication for Use	The specimen retrieval bag is indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.	The specimen retrieval bag is indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.
Configuration	Retracted bag Steel sheet Plug Inner sleeve Outer sleeve Pull ring Outer introducer handle Joint Tightening line Pick rod Inter introducer handle	Retracted Bag Outer Introducer Shaft Outer Introducer Handle Inner Introducer Shaft Inner Introducer Handle String Opening Support Pull loop
Single Use	Single Use	Single Use
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801
Retracted Bag Size	Available in 90mm×100mm, 90mm ×120mm, 90mm×140mm, 90mm ×160mm, 90mm×180mm, 110mm ×120mm, 110mm×150mm, 110mm ×180mm, 130mm×150mm, 130mm×180mm	Available in 40 × 130mm, 60 × 150mm, 80 × 200mm, 100 × 220mm, 130×250mm, 40×150mm, 60×180mm, 80× 220mm, 100× 275mm, 130× 320mm
Retracted Bag Volume	Available in 50ml, 100ml, 120ml, 150ml, 200ml, 250ml, 300ml, 320ml, 350ml, 420ml	Available in 50ml, 100ml, 200ml, 300ml, 350ml, 400ml, 500ml, 600ml
Patient -contact material		
Retracted Bag	Thermoplastic Polyurethane (TPU)	Thermoplastic Polyurethane (TPU)
Outer Introducer Shaft	Polyvinyl chloride (PVC)	Polycarbonate (PC)

Inner Introducer Shaft	Polyvinyl chloride (PVC)	Polycarbonate (PC)
Steel sheet	304 Stainless Steel	/
Plug	Acrylonitrile Butadiene styrene (ABS)	/
Joint	Acrylonitrile Butadiene styrene (ABS)	/
Ttightening line	Nylon	/
Pick rod	Polyvinyl chloride (PVC)	/
Biocompatibility		
Cytotoxicity	No cytotoxicity	No cytotoxicity
Skin Sensitization	No skin Sensitization	No skin Sensitization
Irritation	No irritation	No irritation
Systemic Toxicity	No systemic Toxicity	No systemic Toxicity
Pyrogen	No pyrogen	No pyrogen
Sterilization		
Method	EO sterilization	EO sterilization
SAL	10^{-6}	10^{-6}

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.