August 6, 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: K201641
Trade/Device Name: Disposable Laparoscope Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 27, 2020
Received: June 16, 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)*
K201641

Device Name
Disposable Laparoscope Trocar

Indications for Use *(Describe)*
The Disposable Laparoscope Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.

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.

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: K201641

1. Date of Preparation: 08/06/2020

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. Huifan Wang (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Disposable Laparoscope Trocar
Common Name: General& Plastic Surgery

Regulatory Information
Classification Name: Endoscope and Accessories
Classification: II;
Product Code: GCJ;
Regulation Number: 21CFR 876.1500
Review Panel: General& Plastic Surgery;

Indication for Use:
The Disposable Laparoscope Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.

Device Description:
The proposed device is a basic equipment used during laparoscopic surgical, and the surgical device will enter into abdominal cavity via the passage established by the trocar. The proposed device is available in 5mm, 10mm, 12mm, 15mm four diameters to accommodate different sizes surgical instrument.

5. Identification of Predicate Device

510(k) Number: K180208
Product Name: Disposable Endoscopic Trocar

6. Identification of Reference Device

510(k) Number: K032676
Product Name: Endopath Bladeless Trocar

7. 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 test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-7:2008 Biological Evaluation of Medical Device- Part 7: Ethylene Oxide Sterilization Residuals

- USP <85> Bacterial Endotoxin Limit
- ASTM F88/F88M-15 Standard Test Method For Seal Strength Of Flexible Barrier Materials.(Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization
- ISO 10993-11:2017 Biological Evaluation of Medical Device- Part 11: Tests for Systemic Toxicity

Bench tests were conducted on the proposed device and predicate device, which include

- Instrument Insertion and Removal Forces Test
- Leak Resistance Test
- Snap Feature Retention Force Test

An in vivo study was conducted on porcine model to evaluate the penetration force, fixation force and visualization performance (for optical type only), in addition, tip integrity was also evaluated after each insertion.

Biocompatibility tests were conducted on the proposed device, the test items include Cytotoxicity test, Instracutaneous test, Skin Sensitization, System Toxicity test and Pyrogen Test.

Sterilization and sterile barrier package testing were performed on the proposed device, which include

- EO and ECH residue test
- Endotoxin Limit test
- Seal strength test
- Dye penetration test

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Disposable Laparoscope Trocar

ITEM	Subject Device K201641	Predicate Device K180208	Reference Device K032676
Product Code	GCJ	GCJ	GCJ
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500
Class	II	II	II
Indication for Use	The Disposable Laparoscope Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.	The Disposable Endoscopic Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.	The ENDOPATH Bladeless Trocar has applications in abdominal, thoracic and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.
Main component	Puncture Needle Puncture sleeve Obstruct valve body Injection switch Injection valve Sealing cap Gas barrier seal Lower retaining ring Sealing ring Upper retaining ring Elastic seal ring Fixed cover Positioning guide cover Secure cover	Obturator Obturator Handle Scope locking Cam (Except FLPC5, FLOC10, FLPC12) Obturator Locking Button (housed in obturator handle) Outer Seal Outer Seal Release Lever (Except FLPC5, FLPC10, FLPC12) Stopcock Trocar Smooth Sleeve Trocar Stability Sleeve Optical Element Bladeless Tip	Obturator Sleeve Universal seal Release lever Camera scope-locking tab Recessed stopcock valve Bladeless optical tip
Single Use	Single Use	Single Use	Single Use
Operation Mode	Manually	Manually	Manually
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Complied with 21 CFR part 801
Diameter (mm)	Available in 5, 10, 12 and 15	Available in 5, 10 and 12	Available in 5, 8, 11 and 12
Length (mm)	Available in 96, 98, 99 and 111	100	Available in 75, 100 and 150

Patient Contacting component	Puncture Needle Puncture Sleeve	Obturator Trocar Smooth Sleeve Optical Element Bladeless Tip	Obturator Sleeve Bladeless optical tip
Patient Contacting Material	Polycarbonate (PC)	ABS-1, MN, 095-30-16-15/PC/Stainless 12Cr 18Ni9/ Stainless 06Cr19Ni10	Unknown
Biocompatibility			
Cytotoxicity	Comply with ISO 10993 standards	Comply with ISO 10993 standards	Comply with ISO 10993 standards
Sensitization			
Instracutaneous			
System Toxicity			
Pyrogen			
Insertion force (N)	RJTC-A5: Average 2.25 RJTC-A15: Average 4.08	BLTC12: Average 4.2	B5LT: Average 2.35
Removal force (N)	RJTC-A5: Average 6.37 RJTC-A15: Average 10.31	BLTC12: Average 10.19	B5LT: Average 6.27
Leak resistance	No Leakage	No Leakage	No Leakage
Snap feature retention force (N)	RJTC-A5: Average 1.8 RJTC-A15: Average 11.8	BLTC12: Average 11.98	B5LT: Average 1.69
Sterilization			
Method	EO sterilized	Irradiation	Irradiation
SAL	10^{-6}	10^{-6}	10^{-6}
Endotoxin Limit	20 EU per device	20 EU per device	20 EU per device

10. Substantially Equivalent (SE) Conclusion

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