December 12, 2017

Changzhou Detain Medical Devices Co., Ltd.
℅ Ethan Liu
RA Specialist
Shanghai Thinkwell Consulting Co., Ltd.
Xinling Rd, 211/6F
Shanghai, 201100
China

Re: K171956
Trade/Device Name: Sterile Endoscope Biopsy Sampling Needle
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: FCG
Dated: October 26, 2017
Received: October 30, 2017

Dear Ethan Liu:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171956

Device Name
Sterile Endoscope Biopsy Sampling Needle

Indications for Use *(Describe)*
The Sterile endoscope biopsy sampling needle is used to sample targeted submucosal and extramural lesions within or adjacent to the tracheobronchial tree or gastrointestinal tract through the accessory channel of an ultrasound endoscope.

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."

Section 5: 510(k) Summary

510(k) Number K

5.1 Date Prepared

December 4, 2017

5.2 Submitter

Company: Changzhou Detian Medical Devices Co., Ltd.
Address: No. 47, North Qingyang Rd., Tianning District, Changzhou City, Jiangsu Province, R. R. China
Telephone: +86-21-60409623
Fax: +86-21-60732022
Website: www.jsczdt.com

5.3 Contact/Consult

Company: Shanghai Thinkwell consulting Co., Ltd.
Website: www.thinkwellmed.com
Contact: Ethan Liu
Telephone: +86-15216699240
Email: xtdeepwater@126.com

5.4 Device

Trade Name: Sterile Endoscope Biopsy Sampling Needle
Model: DT-EN-W7
Common Name: Biopsy Needle
Regulation Number: 21 CFR §876.1075
Classification Name: Gastroenterology-urology biopsy instrument
Product Code: FCG
Classification Panel: Gastroenterology/Urology
Regulatory Class: Class Ⅱ

5.5 Predicate Device

Echotip® Ultra Endobronchial High Definition Ultrasound Needle, Echotip Procore® Endobronchial High Definition Ultrasound Biopsy Needle (Cook Ireland Ltd.) K160229

5.6 Device Description

Sterile endoscope biopsy sampling needle, Model: DT-EN-W7 is mainly composed of needle head, PEEK outer tube assembly, and handle. Sizes are available in 18 - 22 gauge needles. The length of the needles range is between 0 and 80 mm. The needle is used by advancing the entire device to the site of soft tissue sampling through endoscopic channel aperture. The needle is advanced with gentle but firm pressure. Once the needle is in position, stab hard into the tissue and connect the external end of needle tube with aspirator in negative pressure. Retreat the needle head into tube, and get the needle out of the endoscope through the

channel. The sample can then be expelled from the stylet notch.

5.7 Indication for Use

The Sterile endoscope biopsy sampling needle is used to sample targeted submucosal and extramural lesions within or adjacent to the tracheobronchial tree or gastrointestinal tract through the accessory channel of an ultrasound endoscope.

5.8 Technological characteristics

- Smoothness and leakproofness: Needle head can move freely and smoothly in the outer tube. The tip should stay in outer tube after retracement. The pull rod can be fixed apace when operate aspirator and turn it. No air leakage except the air passageway.

- Joint strength: The connect of outer tube and handle ⩾15N, connection of needle head and handle ⩾15N.

- Puncture force: Needle tip should be sharp with maximum puncture force ⩽ 8 N.

- Stiffness and resistance to breakage: Sample needle should have good stiffness with span 15 mm ± 0.1 mm, load 10 N ± 0.1 N, deflection value ⩽ 0.50 mm. Sample needle should have good resistance to breakage with span 17.5 mm ± 0.1 mm, and shall not be broken in the same plane at 20 degrees by two-way repeated bending for 20 times.

- Reducing substance: Compared with the same batch blank contrast solution of the same volume, the $KMnO_4$ solution consumption volume of the test liquid is less than 6.5 mL.

- Total content of heavy metal: The color of test solution is not darker than that of p (Pb2+) = 1 μg/mL standard contrast liquid.

- pH value: Test liquid compared with the same batch blank liquid, the difference of pH value should be ⩽ 1.5.

- Decay Resistance: test results satisfy with request of Class 5.4b after needle head erosion test.

- Compatibility with Endoscope: The sterile endoscope biopsy sampling needles shall go through the channel of endoscope smoothly.

5.9 Substantial Equivalency Summary

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the Sterile Endoscope Biopsy Sampling Needle and the predicate device do not raise any questions regarding its safety and effectiveness. Sterile Endoscope Biopsy Sampling Needle, as designed and manufactured, is as safe and effective as the predicate.

5.10 Non-clinical Testing

5.10.1 Performance Data Summary

Non-clinical comparative performance bench testing was successfully completed to establish substantial equivalence between the proposed Sterile Endoscope Biopsy Sampling Needle and its predicate device Echotip® Ultra Endobronchial High Definition Ultrasound Needle, Echotip Procore® Endobronchial High Definition Ultrasound Biopsy Needle. The following tests were conducted on the Sterile Endoscope Biopsy Sampling Needle:

1. Smoothness and leakproofness
2. Joint strength
3. Puncture force
4. Stiffness and resistance to breakage
5. Reducing substance
6. Total content of heavy metal
7. PH value.
8. Decay Resistance
9. Compatibility with Endoscope

5.10.2 Sterility Testing and Shelf Life Summary

The 2 years shelf life of the proposed Sterile Endoscope Biopsy Sampling Needle has been established in accordance with ASTM F1980-07:2011Standard Guide for Accelerated Aging of Sterile Barrie System for Medical Device. The sterility testing has been conducted in accordance with ISO 11737-2:2009 Sterilization of Medical Devices – Microbiological Methods – Part 2: Test of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process after shelf life study and proved package can keep the product sterile during the shelf life after product sterilization process.

5.10.3 Biocompatibility Testing Summary

The proposed Sterile Endoscope Biopsy Sampling Needle was evaluated biocompatibility in accordance with ISO 10993-1:2009 Evaluation and Testing. The following tests were performed with acceptable results on the patient contacting portions of the Sterile Endoscope Biopsy Sampling Needle: Cytotoxicity, Sensitization, Irritation, Systemic Toxicity and material-mediated Pyrogenicity test.

5.10.4 Animal Testing Summary

Animal testing has been conducted by using Sterile Endoscope Biopsy Sampling Needle and Echotip Ultra/Procore Endobronchial High Definition Ultrasound Needle in pigs. And the results demonstrate that the proposed device has the substantial equivalent performance on biopsy sampling with the predicate device.

5.11 Conclusion

The Sterile Endoscope Biopsy Sampling Needle is as safe and effective as the predicate device. It has the same or similar intended use, indications for use, technological characteristics, and principles of operation as those of the predicate device. The minor differences between the Sterile Endoscope Biopsy Sampling Needle and its predicate device raise no new issues of safety or effectiveness. Thus, the Sterile Endoscope Biopsy Sampling Needle is substantially equivalent to its predicate device.