March 5, 2018

Micro-Tech (Nanjing) CO., Ltd.
Becky Li
Quality and Regulatory Affairs Director
NO. 10 Gaoke Third Road
Nanjing, Jiangsu 210032
China

Re: K172663
Trade/Device Name: Cytology Brush
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDX
Dated: January 31, 2018
Received: February 2, 2018

Dear Becky Li:

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,

Charles Viviano -S

For 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)*

K172663

Device Name
Cytology Brush

Indications for Use *(Describe)*
The Cytology Brush is used to collect cells from the bronchi and upper and lower gastrointestinal tracts.

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 2

510K Summary

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

The assigned 510(k) Number: **K172663**

1. **Date of Preparation: 2018-01-02**

2. **Sponsor Identification**

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, PRC

Establishment Registration Number: 3004837686

Contact Person: Becky Li

Position: Quality and Regulatory Affairs Director

Tel: +86-25-58646378

Fax: +86-25-58350006

Email: ln@micro-tech.com.cn

3. **Identification of Proposed Device**

Trade Name: Cytology Brush

Common Name: Endoscopic Cytology Brush

Regulatory Information

Classification Name: Endoscopes and Accessories

Classification: 2

Product Code: FDX

Regulation Number: 876.1500

Review Panel: Gastroenterology/Urology

Intended Use Statement:

The Cytology Brush is used to collect cells from the bronchi and upper and lower gastrointestinal tracts.

4. Identification of Predicate Device

510(k) Number: K896318

Product Name: Wilson-Cook Cytology Brush

Manufacturer: Wilson-Cook Medical, Inc.

5. Indications for Use

The Cytology Brush is used to collect cells from the bronchi and upper and lower gastrointestinal tracts.

6. Device Description

The main component of the proposed device is Brush Head, Outer Sheath and Handle. The main operation is move the Finger Ring back and forth to achieve the movement of Brush Head, then the Brush Head can collect cells from the target site.

The proposed device has seven (7) specifications, the main differences of these specifications are Diameter of Brush Head, Diameter of Outer Sheath and Working Length, Color of Finger Ring.

The proposed devices are EO sterilized to achieve the Sterility Assurance Level (SAL) of 10^{-6} and placed in a sterility maintenance package to ensure a shelf life of 2 years.

7. Comparison of Technological Characteristics

The Cytology Brush of Micro-Tech (Nanjing) CO., Ltd. incorporates substantially equivalent materials, design, configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate devices (K896318).

8. Performance Data

The proposed device **Cytology Brush** meets the requirements of AAMI ANSI ISO 10993-1 :2009/(R)2013 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within A Risk Management Process”, ISO 11135:2014 “Sterilization of Health Care products - Ethylene Oxide - Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices”, and ISO 10993-7 Second Edition 2008-10-15 “Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals [Including: Technical Corrigendum 1 (2009)]”.

The device specific guidance document was consulted in preparing this premarket submission, <Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology>. Performance testing such as Dimension Testing, Tensile Strength Testing and etc, were performed.

The testing performed demonstrated that the proposed device meets the same performance requirements and is Substantially Equivalent (SE) to the currently cleared predicate device (K896318).

9. Clinical Test Conclusion

Clinical Test is not applicable for the proposed device. No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the **Cytology Brush** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate devices (K896318).