July 28, 2022

Zhejiang Chuangxiang Medical Technology Co., Ltd.
Lucius Long, RA Manager
Room 101, 201, 301, 401, 501, Building 50, No.650 Hongfeng
Road Donghu Street, Yuhang District
Hangzhou, Zhejiang Province 311100
CHINA

Re: K220063
Trade/Device Name: Single Use Cytology Brush
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDX
Dated: June 21, 2022
Received: June 28, 2022

Dear Lucius Long:

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,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K220063

Device Name
Single Use Cytology Brush

Indications for Use *(Describe)*
This device is used to enter human gastrointestinal tract (stomach or duodenum) via endoscope to collect cells.

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.

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Zhejiang Chuangxiang Medical Technology Co., LTD.

Section 5 510(k) Summary(21CFR 807.92)

1. Submitter's information

Name: Zhejiang Chuangxiang Medical Technology Co., LTD.

Address: Room 101,201,301,401,501, Building 50, No.650 Hongfeng Road Donghu Street, Yuhang District, Hangzhou City, Zhejiang Province, 311100, P.R. China

Contact person: Lucius.Long
Email： lucius.long@med-nova.com
Telephone: 86-571-89167088
Fax: 86-571-89167086

2. Date of Submission

23-Dec-2021

3. Device

Trade/Device Name: Single Use Cytology Brush
Regulation name: Endoscope and accessories
Regulation class: II
Regulation number:876.1500
Panel: Gastroenterology/Urology
Product code: FDX

4. Predicative device

4.1) 510(k) Number: K172663
Device Name: Cytology Brush

5. Device description

The main component of the proposed device is Brush Head, Outer Sheath, Sliding Handle, Thumb ring, Catheter and Steel Wire. The device is expected to use via endoscope to obtain cellular material from the human body. The main operation is move the Finger Ring back and forth to achieve the movement of Brush Head, and then the Brush Head can collect cells from the target site.

The proposed device has twenty-one (21) specifications, the main differences of these specifications are Diameter of Brush Head, Brush Length, Outer Sheath OD and Effective Length.

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 3 years.

6. Indications for use

This device is used to enter human gastrointestinal tract (stomach or duodenum) via endoscope to collect cells.

7. Comparison of Technological Characteristics:

The Single Use Cytology Brush of Zhejiang Chuangxiang Medical Technology Co., LTD. incorporates substantially equivalent materials, design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device (K172663).

8. Performance Data

The proposed device meets the requirements of ISO 10993 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing”, ISO 11135-1 “Sterilization of Health Care products Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices”, and ISO 10993-7 “Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals”

The following bench tests were performed on Single Use Cytology Brush: Appearance, Dimension, Operational performance. The results of all testing were passing.

The testing performed demonstrated that the proposed device meets the same performance requirements and is Substantially Equivalent (SE) to the currently cleared predicate device (K172663).

9. Clinical Test Conclusion

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

10. Conclusions

Based on the indications for use, technological characteristics, and safety and performance testing, the Single Use Cytology Brush has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device (K172663).