July 3, 2025

Guangzhou PINZHI Medical Device Co., Ltd.
% Jie Yang
Consultant
Chonconn Consulting Co., Ltd.
Room 504, Block C
No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
CHINA

Re: K250838
Trade/Device Name: Denudation Pipettes
Regulation Number: 21 CFR 884.6130
Regulation Name: Assisted Reproduction Microtools
Regulatory Class: II
Product Code: MQH
Received: June 3, 2025

Dear Jie Yang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology 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)*
K250838

Device Name
Denudation Pipettes

Indications for Use *(Describe)*

Denudation Pipettes are used for the removal of cumulus oocyte complexes (COC) from an oocyte prior to Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilization (IVF) as well as for the handling of gametes, embryos and biopsied cells (polar bodies, blastomeres and trophectoderm) during assisted reproductive techniques (ART). Denudation Pipettes are not intended for biopsy of cells from oocytes or embryos.

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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510(k) Summary
K250838

510(k) Owner

Guangzhou PINZHI Medical Device Co.,
Room 405, 4th Floor, No.600-2 Guangshan 2nd Road,Fenghuang Street, Tianhe District, Guangzhou, P.R.China
Phone: (8620)85162357
Email: ivfonly@ivfonly.com
Contact person: Hestia Xu
Title: Technical Regulation Manager

Correspondent

Yang Jie, Consultant,
Chonconn Consulting Co., Ltd.
Room 504, Block C No. 1029 Nanhai Avenue, Nanshan District, Shenzhen, Guangdong 518067 CHN
Phone: +86-755 33941160
Email: yangjie@chonconn.com

Date Prepared

July 2, 2025

Product Information

Trade Name	Denudation Pipettes
Common Name	Assisted reproduction micropipette
Regulation Name	Assisted Reproduction Microtools
Regulation Number	884.6130
Regulatory Class	Class II
Product Code	MQH - Microtools, Assisted Reproduction (Pipettes)

Predicate Device

Research Instruments Ltd.
EZ-Tip Vial of 20
K161275

The predicate device has not been subject to a design-related recall.

Device Description

The Denudation Pipettes are extruded polycarbonate capillary tubes that are pulled at one end to form a tapered tip. They have an outer diameter (OD) of 0.9mm at the proximal end and fit into an actuating device. All tips are approximately 90mm in length and depending on the size of the pipette have a volumetric capacity of 18.6-21.9µl.

The Denudation Pipettes are supplied in a range of inner diameter (ID) sizes at the distal end as shown below:

- 80µm, 130µm, 140µm, 150µm, 160µm, 170µm, 180µm, 190µm, 210µm, 230µm, 250µm, 270µm, 290µm.

The Denudation Pipettes are radiation sterilized and provided in a sterile pouch, supplied in two packaging options. Each pouch contains 5 or 10 pipettes. All pipettes are intended for single use and disposable.

Indications for Use

Denudation Pipettes are used for the removal of cumulus oocyte complexes (COC) from an oocyte prior to Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilization (IVF) as well as for the handling of gametes, embryos and biopsied cells (polar bodies, blastomeres and trophectoderm) during assisted reproductive techniques (ART). Denudation Pipettes are not intended for biopsy of cells from oocytes or embryos.

COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below provides a comparison of the intended use and technological characteristics of the subject device and predicate device:

Characteristic	**Subject device** **Denudation Pipettes** **K250838**	**Predicate device** EZ-Tip Vial of 20 **K161275**	**Comments**
Indications for use	Denudation Pipettes are used for the removal of cumulus oocyte complexes (COC) from an oocyte prior to Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilization (IVF) as well as for the handling of gametes, embryos and biopsied cells (polar bodies, blastomeres and trophectoderm) during assisted reproductive techniques (ART). Denudation Pipettes are not intended for biopsy of cells from oocytes or embryos.	EZ-Tip pipettes are for denudation, i.e. removing the cumulus from an oocyte prior to Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilization (IVF) and for handling gametes, embryos and biopsied cells (polar bodies, blastomeres and trophectoderm) during assisted reproductive techniques (ART). EZ Tips are not intended for biopsy of cells from oocytes or embryos.	Same
Materials	Polycarbonate	Polycarbonate	Same
Sterility	Sterile (10^{-6}) Gamma Irradiated	Sterile (10^{-6}) Gamma Irradiated	Same
Proximal Outer Dimension	900 µm	900 µm	Same

Distal Inner Diameter	Size range 80 µm to 290 µm	Size range 75 µm to 600 µm	**Different** The subject device is within the cleared range of the predicate device. This difference does not raise different questions of safety or effectiveness.
Length	90mm	90mm	Same
Mouse Embryo Assay(MEA)	1-Cell MEA ≥80% Expanded blastocysts at 96 h	1-Cell MEA ≥80% expanded blastocysts at 120 h	**Different** The Mouse Embryo Assay (MEA) assessment time is shorter for the subject device, but it is the standard assessment time for this assay. Therefore, this difference does not raise different questions of safety or effectiveness.
Endotoxin(LAL)	<0.5 EU/device	<20 EU/device	**Different** The endotoxin specification for the subject device is lower than the predicate device. This difference does not raise different questions of safety or effectiveness.
Usage	Single Use	Single Use	Same

As shown in the table above, the subject and predicate devices have same indications for use statements and the intended uses of the predicate and subject devices are the same (i.e., denudation of oocytes and handling of oocytes and embryos during assisted reproduction technology procedures). In regards to technological characteristics, the subject and predicate devices have similarities (e.g., material, length, diameter at the proximal end, sterilization method, etc.); however, as noted in the table above, technological differences were identified between the subject and predicate devices (e.g., distal end tip diameter and specifications for MEA and endotoxin testing). The technological differences between the subject and predicate device do not raise different questions of safety and effectiveness.

Non-Clinical Performance Testing

The following performance tests were performed in support of substantial equivalence:

1. Sterilization Validation per ISO 11137-1:2006 and ISO 11137-2:2013

2. Package Integrity Testing after Simulated transportation (ASTM D4169-23) & Accelerated aging (ASTM F 1980-21):
    a. Visual test of package integrity (ASTM F1886/F1886M-16),
    b. Dye penetration (ASTM F1929-23), and
    c. Seal strength testing (ASTM F88/F88M-23)

3. Shelf Life testing assessing device function at Time 0 and at 36 months:
    a. Simulated transportation (ASTM D4169-22)
    b. Accelerated aging (ASTM F 1980-21)
    c. One-cell mouse embryo assay (MEA): ≥ 80% embryos developed to expanded blastocyst at 96 hours per the 2021 FDA guidance Mouse Embryo Assay for Assisted Reproduction Technology Devices.
    d. Endotoxin (LAL, USP<85>): <0.05 EU/device
    e. Device dimension validation
    f. Appearance & Physical property validation

Conclusion

The results of the testing described above demonstrate that the Denudation Pipettes is as safe and effective as the predicate device and supports a determination of substantial equivalence.