



April 28, 2026

Sheng Sheng Yi (Beijing) Technology Company Limited
Wei Zhao
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China

Re: K260194
Trade/Device Name: Vacuum Pump (Model: AD-VPUM-500)
Regulation Number: 21 CFR§ 884.6120
Regulation Name: Assisted Reproduction Accessories
Regulatory Class: II
Product Code: MQG
Dated: January 22, 2026
Received: January 22, 2026

Dear Wei Zhao:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

510(k) Number (if known)

K260194

Device Name

Vacuum Pump (Model: AD-VPUM-500)

Indications for Use (Describe)

The Vacuum Pump (Model: AD-VPUM-500) is intended for the aspiration of oocytes, during assisted reproduction procedures using low flow, intermittent vacuum.

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.

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510(k) Summary

K260194

I. Submitter Information

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Address: Room 201, Building 4, No. 25 Yanqi 4th South Street, Huairou District, 101400 Beijing, China
Contact Person: Wei Zhao
Phone: +86 10 62927009
E-mail: zhaow@fertsy.com

II. Date of Preparation: April 24, 2026

III. Subject Device Information

Device Trade Name: Vacuum Pump (Model No.: AD-VPUM-500)
Common Name: Vacuum Pump
Regulation Number: 21 CFR 884.6120
Regulation Name: Assisted Reproduction Accessories
Regulation Class: II
Product code: MQG (Accessory, Assisted Reproduction)

IV. Predicative Device

Submission Number: K160753
Device Trade Name: COOK Vacuum Pump

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

V. Device Description

The Vacuum Pump (Model: AD-VPUM-500) is an electrically powered vacuum pump that is used for the collection of oocytes from ovarian follicles for use during in vitro fertilization (IVF) procedures. The Vacuum Pump (Model: AD-VPUM-500) provides vacuum levels ranging from -10 mmHg to -500 mmHg. It is supplied non-sterile.

This device is used in conjunction with a disposable vacuum line with hydrophobic filter, collection tube, and oocyte retrieval needle to perform puncture under transvaginal ultrasound guidance. Through intermittent high vacuum and low flow provided by the Vacuum Pump (Model: AD-VPUM-500), follicular fluid and oocytes from the follicles are aspirated.

The product consists of the main control unit, the power connection cable, and the foot pedal. All other devices, including a disposable vacuum line with hydrophobic filter, collection tube, and oocyte retrieval needle, are not included in the Vacuum Pump

(Model: AD-VPUM-500).

VI. Indications for Use

The Vacuum Pump (Model No.: AD-VPUM-500) is intended for the aspiration of oocytes, during assisted reproduction procedures using low flow, intermittent vacuum.

VII. Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Devices

The table below compares the intended use and technological characteristics of the subject and predicate device.

Attribute	Subject device (K260194)	Predicative device (K160753)	Comparison
Manufacturer	Sheng Sheng Yi (Beijing) Technology Company Limited	William A. Cook Australia Pty Ltd	/
Trade name	Vacuum Pump (Model No.: AD-VPUM-500)	COOK Vacuum Pump	/
Regulation name	Assisted Reproduction Accessories	Assisted Reproduction Accessories	Same
Regulatory Class	II	II	Same
Product code	MQG	MQG	Same
Clinical characteristics			
Indications for Use	The Vacuum Pump (Model No.: AD-VPUM-500) is intended for the aspiration of oocytes, during assisted reproduction procedures using low flow, intermittent vacuum.	The COOK Vacuum Pump is intended for the aspiration of eggs (ova), during assisted reproduction procedures using low flow, intermittent vacuum.	Same
General technological characteristics			
Device design	The Vacuum Pump (Model No.: AD-VPUM-500) is an electrically-powered vacuum pump that is used for the collection of oocytes from ovarian follicles for use during in vitro fertilization (IVF) procedures. The Vacuum Pump (Model	The Vacuum Pump is designed to maintain a vacuum accurately at a user specified setting with a range of -10 mmHg to -500 mmHg when configured to display mmHg and a range of -1.0 kPa to -67.0 kPa when configured to display kPa. The device van also boost the	Different

Attribute	Subject device (K260194)	Predicative device (K160753)	Comparison
	<p>No.: AD-VPUM-500) provides vacuum levels ranging from -10 mmHg to -500 mmHg (-1.0 kPa to – 67.0 kPa). It is supplied non-sterile. This device is used, in conjunction with a disposable vacuum line with hydrophobic filter, collection tube, and oocyte retrieval needle to perform puncture under transvaginal ultrasound guidance. Through intermittent high vacuum and low flow provided by the Vacuum Pump (Model No.: AD-VPUM-500), follicular fluid and oocytes from the follicles are aspirated. The product consists of the main control unit, the power connection cable, and the foot pedal. All other devices, including a disposable vacuum line with hydrophobic filter, collection tube, and oocyte retrieval needle, are not included in the Vacuum Pump (Model No.: AD-VPUM-500).</p>	<p>vacuum to – 500 mmHg (or – 67.0 kPa in kPa display mode) from any setting. The disposable Vacuum Line and Filter (K-DVLF-240) consists of a one-way hydrophobic filter and 240 cm long low volume vacuum line. The Disposable Vacuum Line and Filter is used to connect ovum aspiration needles to the Cook Vacuum Pump to prevent contamination of the unit. It is supplied sterile in peel-open packages and is intended for single-use.</p>	
<p>Working principle</p>	<p>The Vacuum Pump (Model No.: AD-VPUM-500) is an integrated system based on the generation, transmission, and control of negative pressure. Its core power</p>	<p>A single diaphragm pump is attached to a motor. The suctioned air is collected in the pressure reservoir. A pressure gauge is connected to the pressure reservoir and the pressure is displayed. The</p>	<p>Same</p>

Attribute	Subject device (K260194)	Predicative device (K160753)	Comparison
	<p>comes from a diaphragm pump, which actively expels air through the reciprocating motion of the diaphragm, creating a negative pressure environment inside the pump and providing basic power for suction. To maintain stable negative pressure, a pressure sensor is integrated into the pipeline. The system reads the pipeline pressure value, sends it together with the set pressure value to the PID (Proportional-Integral-Derivative) controller for calculation, and the result provides data support for the control of the diaphragm pump. Additionally, the system is equipped with an air tank to buffer pressure fluctuations and reduce sudden pressure changes during the suction process.</p> <p>A foot pedal-controlled stop valve is used to open or close the access of the oocyte retrieval needle, ensuring controllability of the suction process. For safety and sample purity, the system is equipped with multi-stage filters at key nodes to prevent microorganisms and</p>	<p>aspiration pressure sensor detects the set aspiration pressure and the aspiration pressure during the boost operation. A motor controlled by an aspiration pressure control circuit adjusts the detected pressure and maintains the set pressure.</p>	

Attribute	Subject device (K260194)	Predicative device (K160753)	Comparison
	particles from contaminating the sample or damaging the equipment.		
Power supply	Power Supply and Frequency: 100 - 240 VAC, 50 - 60 Hz Max Current: 500 mA (115 VAC); 250 mA (240 VAC) Maximum power consumption: 60 VA	Power Supply and Frequency: 100 - 240 VAC, 50 - 60 Hz Max Current: 500 mA (115 VAC); 250 mA (240 VAC) Maximum power consumption: 60 VA	Same
Operating & storage environment	Environmental operating conditions: +5°C ~ +35°C 30% ~ 75% RH no condensing 79 kPa ~ 106 kPa Storage and transportation directions: +5°C ~ +40°C 5% ~ 75% RH non-condensing 80 kPa ~ 106 kPa	Environmental operating conditions: +5°C ~ +35°C 10% ~ 75% RH no condensing 700 hPa ~ 1060 hPa Storage and transportation directions: +5°C ~ +40°C 10% ~ 75% RH non-condensing	<i>Similar</i>
Ingress Protection degree	IP42	IP41	<i>Different</i>
Recommended flow rate	20-25 mL/min	20-25 mL/min	Same
Vacuum range accuracy	± 5 mmHg (or ±0.7 kPa)	± 5 mmHg (or ±0.7 kPa)	Same
Maximum Pressure in Boost Mode	-500 mmHg or -67 kPa	The vacuum can be boosted to -500 mmHg from any setting during operation	Same
Foot pedal	Yes	Yes	Same
Controller	Microprocessor electronic control	Microprocessor electronic control	Same
Software	Yes	Yes	Same

The subject and predicate devices have the same indications for use and intended use. They also use the same fundamental technology to create a vacuum and have the same

recommended flow rate for oocyte aspiration procedures. The subject device and predicate device differ in ingress protection degree and operating/storage environment. These differences do not raise different questions of safety and effectiveness.

VIII. Summary of Non-clinical Performance Testing

The following performance tests were conducted on the Vacuum Pump (Model No.: AD-VPUM-500) to verify that the subject device met all design specifications, demonstrated performance, and to support substantial equivalence to the predicate device:

Electric Safety and Electromagnetic Compatibility

- ANSI AAMI ES60601-1: 2005 + A1:2012 + A2: 2021, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- IEC 60601-1-2: 2014 + A1: 2020, *Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance -Collateral Standard: Electromagnetic disturbances -Requirements and tests*
- IEC TS 60601-4-2:2024, *Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems*
- 2022 FDA Guidance Document, *Electromagnetic Compatibility (EMC) of Medical Devices*

Software validation

Software Verification and Validation was conducted and documented at a Basic Documentation Level according to the 2023 FDA Guidance Document, *Content of Premarket Submissions for Device Software Functions*

Bench Performance

The following performance testing was conducted on the subject device after worst-case conditioning:

- Visual inspection
- Vacuum pressure parameters (e.g., range, accuracy, etc.).
- Boost mode

The subject device met the specifications for all the testing conducted. The testing was conducted in accordance with the following standards:

- ISO 10079-1: 2022, *Medical suction equipment Part 1: Electrically powered suction equipment*
- ISO 10079-4: 2021, *Medical suction equipment Part 4: General requirements*

IX. Conclusion

The results of the performance testing described above demonstrate that the Vacuum

Pump (Model No.: AD-VPUM-500) is as safe and effective as the predicate device and supports a determination of substantial equivalence.