August 19, 2026

CooperSurgical, Inc.
Ewa Paterson
Senior Regulatory Affairs Specialist
95 Corporate Drive
Trumbull, CT 06611

Re: K261083
Trade/Device Name: Wallace® Aspiration Pump (WAPV1); Wallace® Pump Filter Connector (WFC); Wallace® Vacuum Connection Kit (WVCK)
Regulation Number: 21 CFR§ 884.6120
Regulation Name: Assisted Reproduction Accessories
Regulatory Class: II
Product Code: MQG
Dated: July 17, 2026
Received: July 20, 2026

Dear Ewa Paterson:

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

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)*
K261083

Device Name
Wallace® Aspiration Pump (WAPV1); Wallace® Pump Filter Connector (WFC); Wallace® Vacuum Connection Kit (WVCK)

Indications for Use *(Describe)*
The Wallace® Aspiration Pump (WAPV1); Wallace® Pump Filter Connector (WFC); Wallace® Vacuum Connection Kit (WVCK) 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

K261083

1. Submitter Information

Name: CooperSurgical Inc.

Address: 95 Corporate Drive

Trumbull, CT 06611, USA

Contact Person: Ewa Paterson

Phone: +44(0)7816242831

E-mail: ewa.paterson@coopersurgical.com

2. Date of Preparation: August 18, 2026

3. Subject Device Information

Device Trade Name: Wallace® Aspiration Pump (WAPV1); Wallace® Pump Filter Connector (WFC); Wallace® Vacuum Connection Kit (WVCK)

Common Name: Vacuum Pump

Regulation Number: 21 CFR 884.6120

Regulation Name: Assisted Reproduction Accessories

Regulatory Class: II

Product Code: MQG (Accessory, Assisted Reproduction)

4. Predicative Device

Submission Number: K160753
Device Trade Name: COOK Vacuum Pump

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

5. Device Description

The Wallace® Aspiration Pump (WAPV1) provides vacuum within the operating range of -20 mmHg to -300 mmHg, when configured to display mmHg and a range of -2.7 to -40 kPa when configured to display -kPa. The device holds the target vacuum level within a tolerance ±5 mmHg

or ±0.7 kPa. The unit includes an option of "Clear Needle" mode that can generate a vacuum up to -500 mmHg (±20 mmHg) when configured to display -mmHg and -67 kPa (±-2.7 kPa) when configured to display - kPa.

The Wallace® Aspiration Pump (WAPV1) is designed to provide vacuum to the oocyte recovery set (Dual and Single Lumen) via tubing that allows oocytes to be drawn into the needle and from there into the collection tube. The pump is electrically operated and provides adjustable control for the vacuum level. The suction is activated by a foot-pedal connected to the pump, by the user performing the procedure.

The device is recommended to be used with connection accessories that are offered in two options: Wallace® Pump Filter Connector (WFC) and Wallace® Vacuum Connection Kit (WVCK). Wallace® Filter Connector (WFC) and Wallace® Vacuum Connection Kit (WVCK) are intended to connect the Wallace® Oocyte Recovery Set (Single and Dual Lumen) to the Wallace® Aspiration Pump (WAPV1) when used for aspiration of oocytes during Assisted Reproductive Technology (ART) procedures for infertility treatment. Wallace® Vacuum Connection Kit (WVCK) and Wallace® Filter Connector (WFC) are sterilized via ethylene oxide (EO). The Wallace® Pump Filter Connector (WFC) and Wallace® Vacuum Connection Kit (WVCK) are single use devices with a shelf-life of two years.

6. Indications for Use

The Wallace® Aspiration Pump (WAPV1); Wallace® Pump Filter Connector (WFC); Wallace® Vacuum Connection Kit (WVCK) is intended for the aspiration of oocytes during assisted reproduction procedures using low flow, intermittent vacuum.

7. 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 (K261083)	Predicate device (K160753)
Manufacturer	CooperSurgical Inc.	William A. Cook Australia Pty Ltd
Trade name	Wallace® Aspiration Pump (WAPV1); Wallace® Pump Filter Connector (WFC); Wallace® Vacuum Connection Kit (WVCK)	COOK Vacuum Pump
Regulation name	Assisted Reproduction Accessories	Assisted Reproduction Accessories
Regulatory Class	II	II
Product code	MQG	MQG
Indications for Use	The Wallace® Aspiration Pump (WAPV1); Wallace® Pump Filter Connector (WFC); Wallace® Vacuum Connection Kit (WVCK) 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.
Device design	The Wallace® Aspiration Pump (WAPV1) provides vacuum within the operating range of -20 mmHg to -300 mmHg when configured to display -mmHg, and a range of -2.7 to -40 kPa when configured to display -kPa. The device holds the target vacuum level within the tolerance ±5 mmHg or ±0.7 kPa. The unit includes an option of "Clear Needle" mode that can generate a vacuum up to -500 mmHg (±20 mmHg) when configured to display -mmHg and -67 kPa (±-2.7 kPa) when configured to display -kPa. The device is recommended to be used with connection accessories that are offered in two options: Wallace® Pump Filter Connector	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. In either case, the device will maintain the vacuum within ±5 mmHg (0.7 kPa). The device can also boost the 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

Attribute	Subject device (K261083)	Predicate device (K160753)
	(WFC) and Wallace® Vacuum Connection Kit (WVCK). Accessories for Wallace® Aspiration Pump (WAPV1) are packaged with one device per sterile barrier pouch and the pouched devices contained together in a carton.	Vacuum Pump to prevent contamination of the unit. It is supplied sterile in peel-open packages and is intended for single-use.
Principle of operation	A single diaphragm pump operating at a fixed speed generates negative pressure at the input of a digital pressure regulator. The pressure regulator controls the negative pressure at the output to the user-specified set-point. During the Clear Needle ('boost') operation the pump operates at a higher speed.	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 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.
Vacuum Range	-20 mmHg to -500 mmHg	-10 mmHg to -500 mmHg
Vacuum Range accuracy	±5 mmHg	± 5 mmHg
Recommended flow rate	20–25 ml/min	20-25 mL/min
Boost function	"Clear needle mode" that can generate a vacuum up to -500 mmHg (±20 mmHg) from any setting during operation	The vacuum can be boosted to -500 mmHg from any setting during operation
Accessory Range	2 sterile models (Connector with a hydrophobic filter and Connector with hydrophobic filter and extension tube (length	1 sterile model: Vacuum Line (length 240 cm) with Connector and Hydrophobic Filter

Attribute	Subject device (K261083)	Predicate device (K160753)
	150 cm))	
Foot pedal	Yes	Yes
Controller	Microprocessor electronic control	Microprocessor electronic control
Software	Controlled using microprocessor and software	Controlled using microprocessor and software
USB port	Yes	No
Degree of protection against harmful ingress of solids and water	IP20	IP41
Power Supply	Power Supply and Frequency: 100 – 240 VAC, 50 - 60Hz Max Current: 150 mA (115 VAC); 70 mA (240 VAC) Maximum power consumption: 17 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
Operating & storage environment	Storage and Operating Conditions Temperature: 15°C to 30°C Humidity: 30% to 60% RH Transport Conditions -30 °C to 60 °C 30 % to 90 % Relative Humidity 70 kPa (10 psi) minimum pressure	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

The subject device and predicate device have the same Indications for Use and intended use - the aspiration of oocytes during assisted reproduction procedures using low flow, intermittent vacuum.

The subject and predicate devices use similar technological principles, utilizing a diaphragm pump, microprocessor-based control system, adjustable vacuum generation, foot-pedal activation, and a boost function capable of generating vacuum up to -500 mmHg. Both devices enable a flow rate of 20-25

mL/min and vacuum accuracy of ±5 mmHg. The subject device and predicate device differ in power supply, ingress protection degree, accessories, vacuum range, and operating/storage environment. These differences do not raise different questions of safety and effectiveness.

8. Summary of Non-Clinical Performance Testing

The following non-clinical performance tests were conducted on the Wallace® Aspiration Pump and accessories to verify that the subject device met all design specifications, demonstrated their performance, and to support substantial equivalence to the predicate device:

Electrical 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*.

Cybersecurity

Cybersecurity verification and validation was conducted and documented at a Basic Documentation Level according to the 2026 FDA Guidance Document, *Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions*.

Sterility/Shelf-Life

The Wallace® Vacuum Connection Kit (WVCK) and Wallace® Pump Filter Connector (WFC) are sterilized via Ethylene Oxide method (EO) per ISO 11135:2014 Second edition 2014-07-15, *Sterilization*

of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices.

The shelf-life (stability) and simulated shipping distribution testing for the Wallace® Vacuum Connection Kit (WVCK) and Wallace® Pump Filter Connector (WFC), were conducted in accordance with:

- ISO 11607-1 2019, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including Amendment 1 (2023)]*
- Preconditioning and environmental conditioning per ASTM D4332 2022, *Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing*
- Accelerated Aging per ASTM F1980-21, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*
- Simulated shipping per ISTA 3A 2018, *Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less*
- Visual Inspection per ASTM F1886/F1886M 2016 (2024), *Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection*
- Bubble Leak Test per ASTM F2096 2011(2019), *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization*
- Peel Strength Test per ASTM F88/F88M (2023), *Standard Test Method for Seal Strength of Flexible Barrier Materials*
- Label Integrity Test
- Mechanical Test (Flow rate system test and retention force and pneumatic ingress protection test covering the tensile strength

Bench Performance

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

- Visual inspection
- Vacuum pressure parameter testing (e.g., range, accuracy, etc.)
- Boost mode validation
- OPU (Oocyte Pick-up) simulation test was conducted to validate that the Wallace Aspiration Pump (WAPV1) and accessories in conjunction with Wallace Oocyte Recovery Sets can perform as intended in a simulated use scenario

9. Conclusion

The results of the performance testing described above demonstrate that the Wallace® Aspiration Pump (WAPV1); Wallace® Pump Filter Connector (WFC); Wallace® Vacuum Connection Kit (WVCK) is as safe and effective as the predicate device and supports a determination of substantial equivalence.