August 27, 2025

CooperSurgical, Inc.
Irina Fedorov
Regulatory Affairs Senior Specialist
95 Corporate Drive
Trumbull, CT 06611

Re: K243799
Trade/Device Name: Fetal Pillow
Regulation Number: 21 CFR§ 884.4350
Regulation Name: Fetal Head Elevator
Regulatory Class: II
Product Code: PWB
Dated: July 25, 2025
Received: July 28, 2025

Dear Irina Fedorov:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243799

Device Name
Fetal Pillow

Indications for Use *(Describe)*
Fetal Pillow is intended to elevate the fetal head and facilitate delivery of the fetus in women requiring a Caesarean Section at full dilation or those requiring a Caesarean Section after a failed instrumental vaginal delivery. Fetal Pillow is indicated for use at a gestational age ≥37 weeks.

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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510(k) Summary
K243799
Fetal Pillow

1. Submitter Information

Applicant: CooperSurgical, Inc.
Address: 95 Corporate Drive
Trumbull, CT 06611 U.S.A.

2. Correspondent Information

Company: CooperSurgical, Inc.
Contact: Michael Scott
Email: michael.scott@coopersurgical.com
Phone: 901-827-1855

3. Date prepared: August 28, 2025

4. Device Information

Device Name:	Fetal Pillow
Common Name:	Fetal Pillow
Regulation Number:	21 CFR 884.4350
Regulation Name:	Fetal Head Elevator
Product Code:	PWB (Obstetrics/Gynecology)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	Fetal Pillow
510(k) Number:	DEN150053
Sponsor:	Safe Obstetrics System, Ltd.

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

6. Device Description

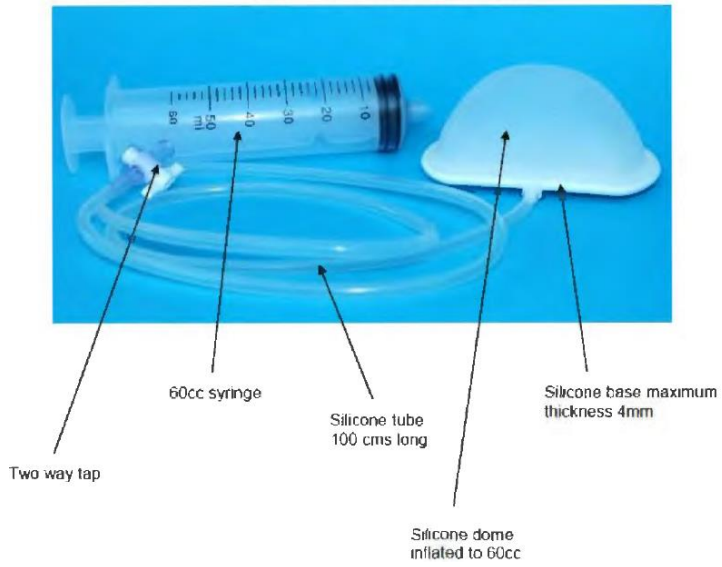
The Fetal Pillow is an inflatable balloon device which consists of the following components:

- Silicone Balloon: Dome shaped balloon attached to base plate, inflated to elevate fetal head.
- Base plate: Oval shaped silicone base plate (9.3cm x 5.0cm) with internal connecting channel to allow attachment to silicone tube.
- Silicone Tube: 4mm tube attaches to connecting channel of base plate for inflation
- Two-way tap: Two-way stopcock at distal end of silicone tube, allows for inflation/deflation of balloon.
- Syringe: 60cc polypropylene syringe attached to distal end of silicon tube, used to inflate balloon with saline solution.

The Fetal Pillow is a single use, disposable, sterile device.

Figure 1 below is an image of the Fetal Pillow

Figure 1. Fetal Pillow



The Fetal Pillow is intended to elevate the fetal head and facilitate delivery of the fetus in women requiring a Cesarean Section at full dilation or those requiring a Cesarean Section after a failed instrumental vaginal delivery. The subject device is a dome shaped, balloon, cephalic evaluation device that enables the elevation of the fetal head to facilitate delivery of the fetus. The inflation and application of the device only occurs under direct control of the user.

The purpose of this 510(k) submission is to update clinical references in the Instructions for Use based on current literature.

7. Indications for Use Statement

Fetal Pillow is intended to elevate the fetal head and facilitate delivery of the fetus in women requiring a Caesarean Section at full dilation or those requiring a Caesarean Section after a failed instrumental vaginal delivery. Fetal Pillow is indicated for use at a gestational age ≥37 weeks.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

Device & Predicate Device(s):	K243799	DEN150053	Comparison
Proprietary name	Fetal Pillow	Fetal Pillow	Same
Device Classification Name Regulation Number FDA Product Code	Fetal head elevator 884.4350 PWB	Fetal head elevator 884.4350 PWB	Same
Indications for use	Fetal Pillow is intended to elevate the fetal head and facilitate delivery of the fetus in women	Fetal Pillow is intended to elevate the fetal head and facilitate delivery of the fetus in women	Same

	requiring a Caesarean Section at full dilation or those requiring a Caesarean Section after a failed instrumental vaginal delivery. Fetal Pillow is indicated for use at a gestational age ≥37 weeks.	requiring a Caesarean Section at full dilation or those requiring a Caesarean Section after a failed instrumental vaginal delivery. Fetal Pillow is indicated for use at a gestational age ≥37 weeks.	
Single use/reusable	Single Use	Single Use	Same
Device operation	Requires direct control by physician user or on their order to inflate the balloon via sterile saline	Requires direct control by physician user or on their order to inflate the balloon via sterile saline	Same
Sterilization Method	ETO	ETO	Same
Device Design and Materials	1) one medical grade silicone dome and silicone base plate, 2) tubing and tubing connection (both made of medical grade silicone), 3) two-way stopcock, made of polycarbonates and polyethylene 4) syringe made of polypropylene and isoprene.	1) one medical grade silicone dome and silicone base plate, 2) tubing and tubing connection (both made of medical grade silicone), 3) two-way stopcock, made of polycarbonates and polyethylene 4) syringe made of polypropylene and isoprene.	Same

The indications for use of the subject and predicate device are identical and they have the same intended use. The technological characteristics of the subject device are identical to the predicate device and do not raise different questions of safety and effectiveness.

9. Summary Performance Testing

There were no design changes between the subject and predicate device, therefore, no additional performance data was presented as part of this 510(k) submission.

Updates to the device instructions for use were supported by the inclusion of the following references:

- Lassey SC, Little SE, Saadeh M, Patton N, Farber MK Bateman BT, Robinson JN. Cephalic Elevation Device for Second-Stage Cesarean Delivery: A Randomized Controlled Trial. Obstet Gynecol. 2020;135(4):879-884.
- Hanley I, Sivanesan K, Veerasingham M, Vasudevan J. Comparison of outcomes at full-dilation cesarean section with and without the use of a fetal pillow device. Int J Gynaecol Obstet. 2020;150(2):228–233.
- United States Food and Drug Administration. De Novo Classification Request For Fetal Pillow. De Novo Summary (DEN150053). 2015;1-14

10. Conclusion

The information provided demonstrates that the Fetal Pillow is as safe and effective as the predicate device and supports a determination of substantial equivalence.