October 29, 2026

TZ Medical
John Lubisich
President
20497 SW Teton Ave.
Tualatin, Oregon 97062

Re: K262570
Trade/Device Name: TZ Medical Birthing Balloon Kit
Regulation Number: 21 CFR 884.4260
Regulation Name: Hygroscopic Laminaria Cervical Dilator
Regulatory Class: II
Product Code: PFJ
Dated: October 1, 2026
Received: October 1, 2026

Dear John Lubisich:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See

the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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)*
K262570

Device Name
TZ Medical Birthing Balloon Kit

Indications for Use *(Describe)*
The TZ Medical Birthing Balloon Kit is indicated for mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.

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 – K262570

Submitter information

510(k) Owner	TZ Medical
Applicant Address	20497 SW Teton Ave Tualatin OR 97062 United States
Applicant Contact Telephone	(503) 639-0282
Applicant Contact	John Lubisich
Applicant Contact Email	johnl@tzmedical.com

Device Information

Device Trade Name	TZ Medical Birthing Balloon Kit
Common Name	Hygroscopic Laminaria cervical dilator
Classification Name	Hygroscopic Laminaria cervical dilator
Regulation Number	884.4260
Product Code	PFJ (Catheter, Balloon, Dilation Of Cervical Canal Prior To Labor)

Predicate Devices

Predicate #	Predicate Trade Name	Product Code
K131206	Cook® Cervical Ripening Balloon	PFJ

I. Device Description Summary

The subject device is a single-balloon catheter system designed for mechanical dilation of the cervix. The kit includes a 16 Fr, 40 cm silicone catheter with a single silicone balloon capable of holding up to 60 mL, a 30 mL syringe, an adhesive attachment pad, and an optional PEBAX introducer with a soft silicone tip. To place the device, the tip of the catheter is inserted past the lower opening of the cervix until the balloon reaches the internal opening. If additional rigidity is needed during insertion, the optional PEBAX introducer can be slid over the catheter to facilitate placement. The silicone tip is designed to rest against the internal lower end of the cervix to minimize trauma, and it is removed once the device has been successfully placed. The balloon is then inflated with approximately 30 mL of saline via a check valve. Once inflated, tension is applied by positioning the adhesive attachment pad parallel to the catheter on the patient's thigh, aligning the notches on the pad with the notch on the tensioning tab. The physician then secures the tensioning tab to the adhesive pad to maintain the desired level of tension throughout the procedure. This tension facilitates cervical ripening and dilation. The device is designed to dilate the cervix to 3 cm when inflated to 30 mL

II. Indications For Use

The TZ Medical Birthing Balloon Kit is indicated for mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.

III. Comparison of Intended Use and Technological Characteristics of the Subject Device and Predicate Device

The table below outlines a comparison of the intended use and technological characteristics of the subject and predicate device.

Device & Predicate Device(s):	K262570	K131206	Comparison
Indications for Use	The TZ Medical Birthing Balloon Kit is indicated for mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.	The Cook Cervical Ripening Balloon is indicated for mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.	Same
Balloon volume	60 ml	80 ml	Different
Balloon Burst volume	≥ 85 cc	>220 ml	Different
Catheter length	40 cm	40 cm	Same
Catheter diameter Catheter Outer Diameter (OD)	16 French (Fr) (5.33 mm) Catheter Outer Diameter: 6.57-7.23 mm	18 (Fr)	Different
Material: Balloon Catheter Sheath	Balloon: Silicone Catheter: Silicone Catheter Hub: Polypropylene Sheath: Silicone	Silicone	Different
Indwell time	12 hour	Up to 12 hour	Same
Placement assistant	Stylet Introducer	Stylet	Different
Introducer dimensions	Introducer Outer Diameter: 14mm Length: 15 cm	Not provided	N/A
Intended cervix dilation	3 cm	Not provided	N/A
Sterile	Sterile	Sterile	Same

The TZ Medical Birthing Balloon Kit and the Cook® Cervical Ripening Balloon have the same intended use, in that they both facilitate mechanical cervical dilation via the application of force transmitted by a silicone balloon catheter. Both devices utilize a placement assistant to increase catheter stiffness during insertion and employ silicone as a protective material for the assistant device. The subject and predicate device have differing technological characteristics, including different dimensions, materials, balloon burst, balloon volume, and introducers. These differences do not raise different questions of safety and effectiveness.

IV. Summary of Non-Clinical Performance Data

To support substantial equivalence of the subject device, the following performance testing was performed:

Ethylene Oxide Sterilization Validation testing per:

- ISO 11135:2014

Package Integrity testing:

- Visual inspection
- Bubble Leak test per ASTM F2096-11
- Seal Strength testing per ASTM F88/ F88M-23
- Dye Penetration testing per ISO 11607 and ASTM F1929
- Creep testing per ISO 11607
- Burst testing per ISO 11607

Transportation Simulation testing per ASTM D4169-22

Biocompatibility Testing

Biocompatibility tests were conducted on the Birthing Balloon Kit in accordance with ISO 10993-1:2025 10993-1, "Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process" as follows:

- Cytotoxicity (ISO 10993-5: 2009)
- Sensitization (ISO 10993-10: 2021)
- Irritation or Intracutaneous Reactivity (ISO 10993:10)

The results of this testing demonstrated that the subject device is non-cytotoxic, non-irritating, and non-sensitizing.

Performance Bench Testing

The following categories of tests were completed to demonstrate substantial equivalence at the beginning and end of the proposed shelf life:

- Catheter Dimensions
- Surface Characteristics
- Insertion/Removal Forces
- Balloon Dimensions & Burst Test
- Tensioning System Effect on Skin

V. Conclusion

The results of the testing described above demonstrate that the TZ Medical Birthing Balloon Kit is as safe and effective as the predicate device and supports a determination of substantial equivalence.