March 6, 2026

Ford Medtech, LLC
℅ Michele Jans
Principal, Regulatory Consultant
The Jans Group, LLC
4417 New Hope Springs Drive
Hillsborough, North Carolina 27278

Re: K252208
Trade/Device Name: JFord Speculum Sleeve™
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: HIB
Received: January 28, 2026

Dear Michele Jans:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

JASON ROBERTS -S

Jason R. Roberts, 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)*
K252208

Device Name
JFord Speculum Sleeve™

Indications for Use *(Describe)*
The JFord Speculum Sleeve™ is a single use, inflatable vaginal wall retraction sleeve intended for use with a vaginal speculum to dilate the vagina and expose the interior of the vagina and exterior of the cervix during pelvic examinations and other gynecological procedures.

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

1. Submitter

Sponsor Name:	Ford Medtech, LLC
Address:	251 Post Avenue, 2nd Floor
	Westbury, NY 11590
Phone:	(516) 203-4316
Contact Person:	Jacqueline Ford, MD
Date Prepared:	March 5, 2026

2. Device

Name of Device:	JFord Speculum Sleeve™
Common or Usual Name:	Vaginal Speculum
Classification Name:	Speculum, Vaginal, Nonmetal (884.4530)
Regulatory Class:	2
Product Code:	HIB

3. Predicate Device

Predicate Device:	ClearSpec® Single Use Vaginal Speculum (K130046)

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

4. Device Description

The JFord Speculum Sleeve™ is a single use, non-sterile, inflatable vaginal wall retraction sleeve designed for use with single use or reusable vaginal specula (medium or large sizes). The speculum sleeve, while used with a vaginal speculum, provides lateral displacement of vaginal tissue during routine female pelvic examinations or other gynecological procedures. The speculum sleeve is intended to assist the clinician in examination when challenged by redundant vaginal walls.

The speculum sleeve has a bottom blade pocket and top sleeve for the speculum blades and bilateral expandable pouches. Using the supplied 30 mL syringe, the expandable pouches are filled as needed with potable water or saline during use to laterally displace redundant vaginal walls to enable optimal visualization.

5. Indications for Use

The JFord Speculum Sleeve™ is a single use, inflatable vaginal wall retraction sleeve intended for use with a vaginal speculum to dilate the vagina and expose the interior of the vagina and exterior of the cervix during pelvic examinations and other gynecological procedures.

6. Comparison of Technological Characteristics with the Predicate Device

A chart comparing the subject device to the predicate device is provided below.

Table 1. Comparison Chart – Subject and Predicate Devices

Characteristic	Subject Device	Predicate Device (K130046)
Device Name	JFord Speculum Sleeve™	ClearSpec® Single-Use Vaginal Speculum (Impact Innovations LLC)
Classification / Product Code	884.4530 / HIB	884.4530 / HIB
Indications for Use	For use with a vaginal speculum to dilate the vagina and expose the interior of the vagina and exterior of the cervix during pelvic examinations and other gynecological procedures.	To dilate the vagina and expose the interior of the vagina and exterior of the cervix during pelvic examinations and other gynecological procedures.
Prescription Use	Yes	Yes
Usage	Single use	Single use
Sterility	Non-sterile	Non-sterile
Materials	Patient-contacting • Clear polyurethane (sleeve and tubing)	Patient-contacting • Clear polyurethane (sheath) • Polystyrene (speculum)
Design characteristics	• Disposable, flexible sleeve with bottom blade pocket for use with a vaginal speculum to retract vaginal sidewalls • Bilateral expandable pouches are designed to be filled with up to a maximum of 30 mL of potable water or saline to mechanically retract vaginal sidewalls • Flexible tubing is used to inflate both expandable pouches during use	• Disposable vaginal speculum that employs a built-in flexible sheath designed to retract vaginal sidewalls

Characteristic	Subject Device	Predicate Device (K130046)
	• A standard 30mL Luer lock syringe is used to inflate the bilateral expandable pouches with fluid	
Speculum Sizes	Fits commonly used medium and large-sized vaginal specula	Available in small to large sizes

7. Performance Data

The following non-clinical performance data were provided in support of the substantial equivalence determination.

Biocompatibility

The biological evaluation for the JFord Speculum Sleeve™ was conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process," September 8, 2023. The speculum sleeve comes in contact with vaginal mucosa for a duration of less than 24 hours, thus, the following tests were performed:

- Cytotoxicity – ISO 10993-5:2099
- Sensitization – ISO 10993-10:2021
- Vaginal Irritation – ISO 10993-23:2021

Testing results demonstrated that the device is biocompatible. The device is not cytotoxic, is not a sensitizer, and is not a vaginal irritant.

Visualization Study

This study demonstrated that the visualization area of the cervix using the speculum sleeve is equal to or greater than the visualization area of the cervix using the speculum alone under simulated use conditions. Testing was performed at minimum and maximum vaginal diameters and at minimum and maximum vaginal pressures. A visualization target that represented a 30mm cervix was used during testing. Observations also determined that the sleeve's expandable pouches deflated sufficiently to allow removal with the sleeve intact.

Device Cycling

This study demonstrated that the speculum sleeve can withstand five simulated use cycles during setup and use in a single procedure without failures.

Pouch Evaluation and Burst Testing

This study evaluated the performance of the speculum sleeve's expandable pouches and determined the burst volume and burst pressure for the pouches.

Pull Force and Elongation Testing

This study determined the maximum pull forces and elongation that the speculum sleeve can withstand to ensure the device does not tear or break when stretched during clinical use.

Reliability Testing

This study demonstrated that under simulated use conditions the speculum sleeve can withstand the pressures exerted on it without leaking or bursting.

Pouch Pressure Testing

This study demonstrated that the speculum sleeve's expandable pouches do not exert a pressure greater than 60mmHg over the pouch area. The pouches exert minimal pressure when inflated with the maximum volume of fluid under simulated use conditions.

Chemical Solution Compatibility Study

The speculum sleeve was tested and found compatible with the following chemical solutions:

- Acetic acid 5%
- Betadine Solution
- Chlorhexidine 4%
- Lugol's Iodine Solution 5%
- Monsel's Solution (Ferric Subsulfate)
- Saline Solution (0.9%)
- Silver Nitrate
- Water-based Lubricant

This study demonstrated that the speculum sleeve is compatible and chemically resistant to these common solutions it may come in contact with during clinical use. Trichloroacetic Acid at 95% and 10% concentrations was not deemed compatible with the speculum sleeve due to potential material degradation.

Summative Usability Testing

A summative usability validation study was performed to demonstrate that the speculum sleeve can be used by intended users without serious use errors or problems, for the intended use and under the expected conditions of use. The results of this study demonstrate the speculum sleeve is safe and effective for its intended use with minimal self-learning. No new risks were identified during the study and there were no use errors or problems that could result in serious harm which could be eliminated or mitigated through design modifications.

8. Conclusions

The non-clinical performance data confirm that the subject device performs as intended and is as safe and effective as the predicate. Thus, the equivalence assessment and performance data demonstrate substantial equivalence to the predicate in terms of safety and effectiveness.