



September 9, 2025

WOMED SAS  
% Michael Daniel  
President / Regulatory Consultant to WOMED SAS  
Daniel & Daniel Consulting  
340 Jones Lane  
Gardnerville, Nevada 89460

Re: P240015  
Trade/Device Name: Womed Leaf® Resorbable Adhesion Barrier  
Product Code: MCN  
Filed: May 13, 2024  
Amended: May 22, 2025; June 09, 2025

Dear Michael Daniel:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Womed Leaf® Resorbable Adhesion Barrier. This device is intended to reduce the reoccurrence and severity of post-surgical adhesion formation inside the uterus. It is indicated for adult women undergoing hysteroscopic surgery for symptomatic moderate to severe intrauterine adhesions. Based upon the information submitted, the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to all other applicable requirements, including those governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 24 months. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and must include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, under 21 CFR 814.82(a)(9), the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below.

1. The Womed Leaf® Resorbable Adhesion Barrier Post Approval Study is a long-term follow-up of the PREG2 randomized controlled trial.

The PREG2 trial was an international, double blind, randomized controlled trial conducted at 16 sites in Europe and China. There were 160 participants randomized to the intervention (n=75) and control (n=85) arms who contributed to the modified intention-to-treat (mITT) analysis and will be followed-up in the PAS study. Continued follow-up from this study through three (3) years will be used to evaluate the long-term safety of the Womed Leaf device.

At least 85% of the patient cohort in each arm must be followed out to three years post procedure. Follow-up must be conducted once a year for the PAS study (i.e., one, two, and three years).

You must collect and report the following:

Primary endpoint: The primary endpoint is the live birth rate. Live birth rate must be reported at one, two, and three years follow-up. Live birth is defined as the delivery of a live born infant who breathes or shows any other evidence of life, such as heartbeat or movement, and refers to an individual newborn.

Secondary endpoints:

1. Clinical pregnancy rates, whether spontaneous or assisted (ovulation induction, intrauterine insemination; in vitro fertilization (IVF) and embryo transfer (ET)), at one, two, and three years, where clinical pregnancy is defined as the presence of fetal sac or heartbeat confirmed by ultrasound.
2. Average time to first pregnancy (i.e., time between the second look hysteroscopy and estimated date of conception) at one, two, and three years.
3. Pregnancy rate leading to a live birth at one, two, and three years, where pregnancy rate is defined as the presence of fetal sac or heartbeat by ultrasound or a positive urinary test or blood test leading to a live birth.

4. Pregnancy related events at one, two, and three years:
  - a. Miscarriage (intrauterine pregnancy loss before 20 weeks gestation)
  - b. Ectopic pregnancy (defined as pregnancy outside of the endometrial cavity, diagnosed by ultrasound, surgical visualization, or histopathology)
  - c. Retained products of conception
  - d. Termination of pregnancy
  - e. Intrauterine growth restriction
  - f. Premature rupture of the membranes
  - g. Placenta previa
  - h. Premature delivery (defined as a delivery before the 37<sup>th</sup> week of pregnancy)
  - i. Uterine rupture
  - j. Postpartum hemorrhage
  - k. Placenta accreta spectrum (accreta, increta, percreta)
  - l. Intrauterine fetal demise defined as the death of a fetus of at least 20 weeks gestational age
  - m. Other
5. Reintervention rate (repeat adhesiolysis) after second look hysteroscopy up to one year following the index procedure.
6. Average number of adhesiolysis procedures per patient after second look hysteroscopy up to one year following the index procedure.
7. Improvement in menstrual pattern at one, two, and three years compared to baseline. Menstrual pattern is considered improved if menses is resumed for amenorrheic patients or if hypomenorrhea (scant spotting or light period) patients experience an increased duration or increased volume of periods compared to that previously reported.

Data must be summarized descriptively, without statistical testing.

Version 4 of the Womed Leaf Post Approval Study protocol, received via email on September 4, 2025 must be followed.

PAS Progress Reports must be submitted every six (6) months for the first year and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA. The Final PAS Report should be submitted no later than three (3) months after study completion (i.e., last subject's last follow-up date).

Each PAS report should be submitted to the address below identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement, including continued follow-up of your premarket cohort, and completion requirements outlined above, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study

involving human subjects) may be grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post-Approval Studies Program Database Webpage, available at [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma\\_pas.cfm](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm).

In addition, the results from any post approval study should be included in the labeling as these data become available. Under 21 CFR 814.39, any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order" (<https://www.fda.gov/media/71327/download>).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system>.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. Additional information about changes that may require a PMA supplement are provided in the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" <https://www.fda.gov/media/81431/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 and process controls (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR Part 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems> and on combination product post-marketing safety reporting is available at <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>.

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR Part 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found at <https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals>. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Beckilyn Dorsey at (301) 837-7598 or [Rebecca.Dorsey@fda.hhs.gov](mailto:Rebecca.Dorsey@fda.hhs.gov).

Sincerely,

Sharon M. Andrews  
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