July 2, 2026

Claria Medical, Inc.
Brian Fisher
VP, Regulatory, Clinical & Quality
2586 Wyandotte St.
Mountain View, California 94043

Re: DEN250034
Trade/Device Name: Claria System
Regulation Number: 21 CFR 884.4075
Regulation Name: Gynecologic power morcellator and containment system
Regulatory Class: Class II
Product Code: SIM
Dated: July 24, 2025
Received: August 7, 2025

Dear Brian Fisher:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Claria System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Claria System is indicated for contained cutting, coring, and extraction of tissue during laparoscopic hysterectomy. The Claria Container is introduced transvaginally to isolate and contain tissue considered benign during powered bulk tissue reduction with the Claria Bulk Tissue Reducer. When used in women with fibroids, the Claria System is for women who are pre-menopausal and under age 50.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Claria System, and substantially equivalent devices of this generic type, into Class II under the generic name gynecologic power morcellator and containment system.

FDA identifies this generic type of device as:

> **Gynecologic power morcellator and containment system**. A gynecologic power morcellator and containment system is a prescription device consisting of an integrated power morcellator and a containment method that are intended to contain, reduce and remove gynecologic tissue that is not suspected to contain malignancy during minimally invasive surgery.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On August 7, 2025, FDA received your De Novo requesting classification of the Claria System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Claria System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Claria System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation
Infection from lack of sterility	Sterilization validation Shelf life validation Labeling
Intraperitoneal tissue dissemination (benign or malignant) from containment breach leading to: • Spread of occult (unknown) cancer or fibroid fragments • Pain and distension	Clinical performance testing Non-clinical performance testing Software verification, validation and hazard analysis Electrical safety, thermal safety and mechanical safety testing Electromagnetic compatibility testing Labeling Training
Vaginal wound issues (bleeding, clot formation, pain, poor healing), organ injury, or infectious processes from: • Contact with the system components • Electrical shock • Excessive heat generation from the system components • Use error	Clinical performance testing Non-clinical performance testing Software verification, validation and hazard analysis Electrical safety, thermal safety and mechanical safety testing Electromagnetic compatibility testing Labeling Training

Identified Risks to Health	Mitigation Measures
Conversion to mini-laparotomy or open surgery with prolonged anesthesia due to: • Inadequate tissue morcellation • Use error	Clinical performance testing Non-clinical performance testing Labeling Training

In combination with the general controls of the FD&C Act, the gynecologic power morcellator and containment system is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must demonstrate that trained users can deploy the device, morcellate and remove gynecologic tissue, and remove the device while maintaining containment integrity. Testing must evaluate all adverse events.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use to verify and validate the design of the system. The following system performance characteristics must be tested:
   (i) Demonstration of device impermeability to tissue, cells and fluids following morcellation;
   (ii) Demonstration that the device allows for visualization of the instruments used with the system and tissue relative to external viscera during tissue reduction;
   (iii) Demonstration that instruments used with the system do not compromise the integrity of the containment system; and
   (iv) Demonstration of tissue morcellation and extraction under worst-case conditions.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) The patient-contacting components of the device must be demonstrated to be sterile.

(5) Performance data must support shelf life by demonstrating continued sterility of sterile components, package integrity, and device functionality over the labeled shelf life.

(6) Performance testing must demonstrate the electromagnetic compatibility, electrical safety, thermal safety, and mechanical safety of the device.

(7) Software verification, validation, and hazard analysis must be performed.

(8) A training program must be validated and included with sufficient educational elements so that upon completion of the training program, users can deploy the device, morcellate and remove gynecologic tissue, and remove the device while maintaining containment integrity.

(9) Labeling must include:
   (i) A contraindication for use in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy;

(ii) Unless clinical performance data demonstrates that it can be removed or modified, a contraindication for removal of uterine tissue containing suspected fibroids in patients who are: post-menopausal; or over 50 years of age; or candidates for en bloc tissue removal though the vagina or via a mini-laparotomy incision;
(iii) A boxed warning identifying the risk of unsuspected cancer, potential for dissemination and that the use of this device has not been clinically demonstrated to reduce this risk;
(iv) A statement limiting use of the device to physicians who have completed the training program; and
(v) An expiration date or shelf life of the sterile components.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the gynecologic power morcellator and containment system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Veronica A. Cronin at 301-796-6538.

Sincerely,

SHARON M. ANDREWS -S

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
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