April 20, 2023

Empower Medical Devices
% Sharon Bishop
Director of RA
Graematter, Inc.
1324 Clarkson Clayton Ctr, #332
St. Louis, Missouri 63011

Re: DEN220082
Trade/Device Name: Bateman™ Bottle
Regulation Number: 21 CFR 878.4675
Regulation Name: Breast implant suction retrieval system
Regulatory Class: Class II
Product Code: QVS
Dated: November 18, 2022
Received: November 21, 2022

Dear Sharon Bishop:

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 Bateman™ Bottle, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Bateman™ Bottle is a single-patient, single use suction device used to assist in the removal of one intracapsular ruptured silicone breast implant.
> Not intended for en bloc removal. Not intended to remove residual silicone or be applied directly to tissue.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Bateman™ Bottle, and substantially equivalent devices of this generic type, into Class II under the generic name breast implant suction retrieval system.

FDA identifies this generic type of device as:

> **Breast implant suction retrieval system**. A breast implant suction retrieval system is a prescription surgical device that uses vacuum suction to assist in the removal and containment of a ruptured silicone breast implant.

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 November 21, 2022, FDA received your De Novo requesting classification of the Bateman™ Bottle. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Bateman™ Bottle 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 Bateman™ Bottle 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:

Risks to Health	**Mitigation Measures**
Injury to surrounding breast tissue and/or overlying skin from suction due to mechanical fault or malfunction	Animal performance testing Non-clinical performance testing Shelf-life testing Labeling
Injury to surrounding breast tissue and/or overlying skin from suction due to use error	Animal performance testing Non-clinical performance testing Labeling Usability testing
Adverse tissue reaction	Biocompatibility evaluation Sterilization validation Shelf-life testing
Infection	Sterilization validation Shelf-life testing

In combination with the general controls of the FD&C Act, the breast implant suction retrieval system is subject to the following special controls:

(1) Animal performance testing must demonstrate that the device performs as intended and will not result in tissue injury. Testing must:
   (i) Demonstrate the ability to remove implants of the sizes and types specified in device labeling; and

(ii) Assess tissue integrity and injury at multiple time intervals to assess tissue healing response after device use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:
   (i) Characterization of the range of device operation, including minimum and maximum vacuum suction parameters;
   (ii) Durability and integrity testing; and
   (iii) Characterization of control and variation of suction application.

(3) Performance testing must demonstrate the sterility of the device.

(4) Performance testing must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(5) The tissue-contacting components of the device must be demonstrated to be biocompatible.

(6) Usability testing must demonstrate that intended users can correctly use the device, based solely on reading the directions for use.

(7) Labeling must include the following:
   (i) Summary of device specifications, including vacuum suction pressure ranges and bottle capacity; and
   (ii) Sizes and types of implants that can be removed with the device.

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 breast implant suction retrieval 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 systems (QS) regulation (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).

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 Cal Rabang at 301-796-6412.

Sincerely,

David Krause -S

for Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health