DE NOVO CLASSIFICATION REQUEST FOR BATEMAN BOTTLE

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 878.4675

CLASSIFICATION: Class II

PRODUCT CODE: QVS

BACKGROUND

DEVICE NAME: Bateman Bottle

SUBMISSION NUMBER: DEN220082

DATE DE NOVO RECEIVED: November 21, 2022

SPONSOR INFORMATION:

Empower Medical Devices
8964 Little Mountain Road
Mentor, OH 44060

INDICATIONS FOR USE

The Bateman Bottle is indicated as follows:

The Breast Implant Removal System 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.

LIMITATIONS

The sale, distribution, and use of the Bateman Bottle are restricted to prescription use in accordance with 21 CFR 801.109.

Do not use on patients who have undergone prior breast reconstruction.

Do not use on patients who show tissue characteristics that are clinically incompatible with device use, including previous mastectomy, radiation including compromised vascularity or ulceration.

The device is not intended to remove residual silicone in the breast pocket after implant extraction.

The nozzle tip is not intended to be applied to surrounding tissue when suction pressure is on.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The breast implant removal system is a two-piece bottle with a concave shaped nozzle on one end and a tapered fitting port on the opposite end that allows attachment to a vacuum source. The nozzle is placed against the shell of a ruptured implant, and once vacuum suction pressure is applied, the implant and silicone contents are drawn into the bottle.

Figure 1: Schematic image of the Bateman Bottle.

The tank has a tapered port for connection to vacuum tubing that interfaces with a vacuum source. The bottle is intended to be used with a standard OR wall vacuum or a portable surgical aspirator pump.

The nozzle has a "fish-mouth" concave shaped opening to facilitate engagement between the nozzle and the implant, as well as lubricious hydrophilic coating to reduce friction in delivering the implant into the specimen bottle. External contoured features on the bottle aid in the user grip and manipulation of the container. The bottle has vent holes which must be covered to apply suction.

After removing the bulk of the implant, any residual leaked silicone material is removed by conventional techniques such as manual removal/extraction. The tank can be opened for the purpose of implant examination or implant manufacturer return.

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY

The Bateman Bottle, per the patient contact classification and Table A.1 of the FDA Biocompatibility guidance entitled, "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*, is categorized as an external communicating device with limited (<24 hour) tissue contact and the following biocompatibility endpoints were assessed:

Endpoint	Test Method
Cytotoxicity	MEM Elution Test ISO 10993-5:2009
Sensitization	Guinea Pig Maximization ISO 10993-10:2010
Irritation	Intracutaneous Irritation Test ISO 10993-10:2010
Acute Systemic Toxicity	Acute Systemic Injection Test ISO 10993-11:2017
Material-Mediated Pyrogenicity	Rabbit Pyrogenicity Test ISO 10993-11:2017

STERILITY/PACKAGING/SHELF LIFE

The Bateman Bottle is a single-use device provided sterile. The device is sterilized in accordance with ISO 11137-2:2013/R2019 using gamma radiation. The validation testing substantiated a radiation sterilization dose of 25 kGy for a sterility assurance level (SAL) of 10^{-6}.

The primary packaging consists of one bottle placed inside a PETG tray sealed with a Tyvek lid. The shelf-life for the Bateman Bottle has been established at two years based on an accelerated aging study. The Bateman Bottle was evaluated by visual inspection, seal strength per ASTM F88, and bubble leak testing per ASTM F2096-11. The test article met the acceptance criteria for each test.

PERFORMANCE TESTING - BENCH

Bench testing was conducted on the Bateman Bottle to demonstrate that the device performs as expected under the anticipated conditions of use. The following bench testing was conducted to demonstrate the device performance characteristics:

- Implant extraction testing, in breast models, at worst case conditions to demonstrate that the Bateman Bottle can fully aspirate the largest size implant (800cc) with high cohesivity and a 2cm rupture at the lowest recommended suction pressure (300mmHg). Residual silicone is measured by the difference in weights of the implant and bottle after extraction and before implantation.

- Implant extraction testing to demonstrate that the Bateman Bottle can fully aspirate the largest size implant (800cc) with low cohesivity and a 4cm rupture at the highest recommended suction pressure (500mmHg). Worst case conditions are used with respect to likelihood for residual silicone. Residual silicone is measured by the difference in weights of the implant and bottle after extraction and before implantation.

- Design verification to verify device dimensional parameters conformed to specification.

- Bottle access testing to ensure the bottle can be opened following implant extraction.

- Vacuum and vent hole testing to demonstrate the ability of the device to adequately achieve and maintain vacuum. The vent hole testing demonstrates the ability of the device to control and relieve vacuum as needed.

- Bottle testing to demonstrate device integrity during use of the device at or exceeding maximum recommended suction pressure (>500mmHg).

- Design Validation and Usability Testing to demonstrate that the intended user can use the device properly as instructed to retrieve a ruptured silicone implant in a simulated use benchtop model. Intended users performed the critical tasks under simulated use conditions.

PERFORMANCE TESTING - ANIMAL

Performance testing was completed using porcine models to demonstrate that the use of the device for implant retrieval is comparable to manual implant extraction techniques.

A summary of the evaluation and results from this study can be found in Table 3.

Table 2: Animal GLP Study Overview

Test	Purpose	Method	Results
GLP Porcine Study	To evaluate the gross and histopathologic responses of tissue to subject device explant vs. manual device explant of ruptured silicone breast implants	Seven pigs were implanted with 3 pairs of implants (6 total implants per model). At day 30 ± 3 post implant, each pig was	Peri-implant tissue conditions and responses were observed for the following time-points:

	in a Yorkshire Cross Pig Model	anesthetized, and all 6 implants were removed. One of each pair of implants were explanted with the Bateman Bottle and the other was explanted with conventional hand removal techniques. Group 1 (n = 3) animals were euthanized following removal of the implants and tissue collected for histopathology. Group 2 (n = 4) animals had surgical sites for implant removal were closed and animal were recovered. At Day 28 ± 3 post explant, the Group 2 animals were euthanized, and tissues were collected for histopathologic analysis.	• After implantation • At time of explantation • 28 days post-explantation. The test device was able to remove each of the designated implants. The tissue response from the ruptured silicone implant removal with the Bateman Bottle was comparable to the tissue response from manual extraction of the ruptured silicone breast implant.

LABELING

The device user manual include a description of the device technical parameters and instructions for use for the device. The user manual contains acceptable vacuum suction pressure ranges tested for use with the device. A table is included with a description of the implant types, volumes, and shapes extracted in bench and animal testing.

The instructions for use contain the following contraindications:

1) Do not use on patients who have undergone prior breast reconstruction.
2) Do not use on patients who show tissue characteristics that are clinically incompatible with device use, including previous mastectomy, radiation including compromised vascularity or ulceration.

The instructions for use contain the following precautions:

1) Before using the Bateman Bottle, manually free the implant shell from any attachment to the surrounding implant capsule.

2) The recommended suction pressure range for larger implants is 300 to 500mmHg. Smaller implants may require less suction pressure. It is not recommended to exceed 500mmHg.
3) Only connect to a regulated vacuum supply and use the minimum required vacuum.
4) It is recommended the device only be used with inframammary incisions of at least 60mm in length.
5) Only apply suction to implant shell and silicone gel material. Avoid application of suction to surrounding tissue.
6) Do not exceed suction pressure of 500mmHg.
7) Use extra care when tissue is sensitive or friable.

Labeling for this device is in accordance with the special controls listed below.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the Bateman Bottle and the measures necessary to mitigate these risks.

Identified 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

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

Benefits

The probable benefits of the device are based on nonclinical laboratory and/or animal studies described above.

The sponsor has provided preclinical testing to demonstrate the benefit of device use. The testing include product functional testing, animal testing, and design validation/usability testing.

- Functional testing was performed in a simulated breast model with 800cc implants of various silicone cohesivity that were ruptured with 2 cm and 4 cm cuts. The minimum and maximum recommended pressure settings were used.
- Simulated Use/Usability Testing used the same in silico breast model as functional testing. Plastic surgeons were given the device to remove both textured and smooth implants of various sizes.
- A porcine animal study using implanted worst case ruptured implants (small, 200cc volume). Implants were removed either manually or with the device 28 days after implantation. Tissue damage was assessed via histology.

The above testing showed that the device functioned as intended to extract and contain a ruptured silicone implant, minimized exposure and handling of residual silicone, and was properly used in the hands of trained professionals.

The subject device is a sterile bottle shaped apparatus that facilitates the removal and containment of ruptured silicone implants while minimizing the handling of and exposure to residual silicone. Validation testing as demonstrated that this is a method that minimizes surgeon manual contact with the ruptured implant, preventing further leakage of silicone via handling of the implant and reducing the amount of manual contact with breast tissue. In simulated use

testing, the subject device demonstrated removal of implants without residual silicone, calculated by pre- and post-procedure implant weight. Results of the animal study support that the Bateman Bottle extracts and contains a ruptured silicone breast implant and demonstrated no significant difference in tissue damage between the use of device and manual extraction techniques.

Risks

The risks of the device are based on nonclinical laboratory and/or animal studies described above.

Histological tissue samples taken from animal testing using either manual extraction or suction assisted extraction with the device show comparable evidence of tissue injury; there was no significant difference in tissue damage when comparing the two methods of implant extraction. No device related adverse events were observed in the animal study. During manual extraction of tissue adhered ruptured silicone breast implants, there is a known risk of tissue injury. A similar risk of tissue injury is present with use of the subject device. However, tissue adherence was not observed in the animal studies. This is likely due to the limitations of the animal study design. Breast implant adhesion to surrounding tissues occurs over long periods of time and would be expected to be encountered clinically in patients who have had breast implants for years. This was not able to be tested or assessed in the bench and animal studies therefore, a moderate level of uncertainty for the identified risks was determined.

Risks of tissue damage during device use are mitigated with instructions to free the implant shell from any attachment to the surrounding implant capsule prior to device use. The risk of tissue damage is further mitigated by warnings to not use the device for removal of residual silicone and the statement that the device is contraindicated for use in patients who have undergone prior breast reconstruction or show tissue characteristics that are clinically incompatible with device use. This includes patients having had a previous mastectomy or radiation including compromised vascularity or ulceration. Additionally, device use risks and study design limitations are further mitigated with the addition of cautions stating that the device and nozzle should not be applied to surrounding tissue and not to exceed suction pressure maximum of 500mmHg.

Risks of infection and adverse tissue reactions have been tested and found to be mitigated through Biocompatibility testing, sterilization validation, and shelf-life testing. Overall, the identified risks can be appropriately mitigated, and we can conclude that the risk of device use are comparable and not substantially different to the risks of manual extraction of implants by hand.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

> *The Breast Implant Removal System 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.*

The probable benefits outweigh the probable risks for the Bateman Bottle. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Bateman Bottle is granted and the device is classified as follows:

Product Code: QVS
Device Type: Breast implant suction retrieval system
Regulation Number: 21 CFR 878.4675
Class: II