Applied Medical Technology, Inc.
Steven Curtis
Regulatory Affairs Specialist
8006 Katherine Blvd.
Brecksville, Ohio 44141

February 3, 2026

Re: K252438
Trade/Device Name: Explant Express
Regulation Number: 21 CFR 878.4675
Regulation Name: Breast Implant Suction Retrieval System
Regulatory Class: Class II
Product Code: QVS
Dated: January 9, 2026
Received: January 9, 2026

Dear Steven Curtis:

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 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 (21 CFR 820.30 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 systems (QS) regulation (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.02.03 16:17:58 -05'00'

Colin K. Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control 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.

Submission Number *(if known)*

K252438

Device Name

Explant Express

Indications for Use *(Describe)*

The Explant Express™ 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Breast Implant Removal Device

I. SUBMITTER:

Applied Medical Technology, Inc.
8006 Katherine Boulevard
Brecksville, OH 44141
Phone: 440-717-4000
Fax: 440-717-4200

Contact Person: Steven Curtis – Regulatory Affairs Specialist
Email: Steven.Curtis@appliedmedical.net
Date Prepared: August 1, 2025

II. DEVICE INFORMATION:

Trade/Device Name: Explant Express™
Common Name: Breast implant removal device
Classification Name: Breast implant suction retrieval device
Regulation Number: 21 CFR §878.4675
Review Panel: General & Plastic Surgery
Regulatory Class: II
Product Code: QVS

III. IDENTIFICATION OF PREDICATE:

Trade/Device Name: BIRD (previously known as the Bateman Bottle)
Manufacturer: Gaylord Solutions LLC
DeNovo Classification No: DEN220082

The predicate device has not been subject to any design-related recalls.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION:

The Explant Express™ consists of a container with a nozzle and a port for applied suction. The scientific concept that forms the basis for the device is suction. The components of this device consist of two separable container halves and an O-ring.

V. INDICATIONS FOR USE:

The Explant Express™ 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 device is contraindicated for use in patients with prior history of breast reconstruction and patients who show tissue characteristics that are clinically incompatible with device use, including previous mastectomy, radiation including compromised vascularity or ulceration.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The subject device has the same (identical) indications and contraindications for use as the legally marketed predicate device. At a high level, the technological characteristics of both devices are the same. There are no significant differences in design, material, principle of operation, or energy source that raise new or different questions of safety or effectiveness as compared to the predicate. The technological characteristics that define both the subject and predicate devices are:

- Rigid plastic container with a nozzle at one end and a vacuum port at the opposite end.
- Container comprises two separable parts to facilitate retrieval of extracted material.
- Attaches to operating room suction (does not create or transform energy).

The following minor difference exists between the subject and predicate devices:

- The subject device uses an O-ring to provide a fluid-tight seal between the two separable parts of the container. The predicate device does not use an O-ring, instead relying upon an interference fit between rigid plastic components.

There are no new or different questions of safety or efficacy raised by this minor difference.

VII. PERFORMANCE DATA:

Performance testing was conducted to confirm that the subject device meets performance requirements that ensure the level of safety and effectiveness provided is at least as good as the predicate device. The testing information provided complies with the requirements for performance testing specified in the Special Controls established for product code QVS.

1. Software, Interconnectivity, EMC & Electrical Safety:

N/A - Device is purely mechanical; no software, electrical components, or data exchange.

2. Biocompatibility:

The biocompatibility of the tissue contacting components of the subject device was evaluated for limited (≤24 hour) direct contact with tissue/bone in accordance with the

recommendations and requirements of ISO 10993-1 and FDA Guidance on the use of ISO 10993-1. The following endpoints were assessed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity

3. Sterility, Shelf Life, and Packaging:

Validation of the EO sterilization process was performed in accordance with ISO 11135. Testing of sterilant residuals was performed in accordance ISO 10993-7. Shelf-life testing was assessed after sterilization, accelerated aging, and simulated transit testing.

4. Non-Clinical:

Bench testing was conducted to verify the device meets the established requirements that assure a minimum level of safety and efficacy that is at least as good as the predicate device. The following bench testing was performed:

- Implant Extraction Testing
- Vacuum Collapse Testing
- Vacuum Leakdown Testing
- Drop Testing
- Vacuum Tube Retention Testing
- Vacuum Occlusion Testing
- Disassembly Force Testing
- Destructive Testing
- Design Verification Study
- Control Vent Performance Study

Simulated use/design validation testing was conducted in accordance with the FDA guidance document "Design Control Guidance for Medical Device Manufacturers" (issue date: March 1997) to demonstrate that the device specifications conform with the intended use and user needs.

Human factors/usability validation testing was conducted in accordance with the FDA guidance document "Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff" (issue date: February 2016). The device was shown to be easy and intuitive to use following the directions for use, without coaching or instruction.

Animal performance testing was conducted to verify the device performs as intended and will not cause injury or impair wound healing. A GLP animal study was conducted using a

porcine model to challenge the device in a worst-case scenario. Breast implants were placed in the mammary tissue of pigs and intentionally ruptured. The device was successful in removing all designated implants. Tissue integrity and injury following device use were evaluated macroscopically and histologically at multiple time intervals. The evidence from this study supports a conclusion that the device functions as intended and does not result in tissue injury or impaired wound healing following device use.

5. Clinical Study:

No clinical studies were conducted in support of this submission.

VIII. CONCLUSION:

The information provided in this submission supports the conclusion that the Explant Express™ is substantially equivalent to the predicate device with respect to intended use, technical characteristics, performance, and safety, and demonstrates compliance to the special controls established for Product Code QVS.