SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Thermal Endometrial Ablation Device

Device Trade Name: Minitouch 3.8 Era System (Minitouch System)

Device Procode: MNB

Applicant's Name and Address: MicroCube, LLC
47853 Warm Springs Blvd.
Fremont, CA 94539

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P230002

Date of FDA Notice of Approval: July 28, 2023

II. INDICATIONS FOR USE

The Minitouch System is indicated for ablation of the endometrial lining of the uterus for the treatment of menorrhagia (heavy menstrual bleeding) due to benign causes in premenopausal women for whom childbearing is complete.

III. CONTRAINDICATIONS

The Minitouch System is contraindicated for use in the following:

- A patient who is pregnant or who wants to become pregnant in the future. PREGNANCY FOLLOWING ABLATION CAN BE DANGEROUS FOR BOTH MOTHER AND FETUS.
- A patient with known or suspected uterine cancer or pre-malignant conditions of the endometrium, such as unresolved adenomatous hyperplasia.
- A patient with any anatomic condition (e.g., history of previous classical cesarean section or transmural myomectomy, including hysteroscopic and/or laparoscopic myomectomy performed immediately prior to the Minitouch procedure) or pathologic condition (e.g., requiring long- term medical therapy) that could lead to weakening of the myometrium
- A patient with a history of endometrial ablation and/or resection (including endometrial ablation/resection performed immediately prior to the Minitouch procedure), regardless of the modality by which it was performed. REPEAT ABLATION MAY RESULT IN SERIOUS PATIENT INJURY.

- A patient with active genital or urinary tract infection, or pelvic inflammatory disease at the time of treatment.
- A patient who has an abnormal, obstructed, or perforated cavity. ABLATION IN SUCH CAVITIES COULD RESULT IN SERIOUS INJURY.
- A patient who has an intrauterine implant, such as intrauterine device (IUD) currently in place.
- A patient with undiagnosed vaginal bleeding.
- A patient who has uterine cavity length of less than 4 cm. The Handpiece may not deploy adequately and system may not initiate energy delivery.
- A patient who has abnormal uterine/pelvic anatomy, such as frozen pelvis.

IV. WARNINGS AND PRECAUTIONS

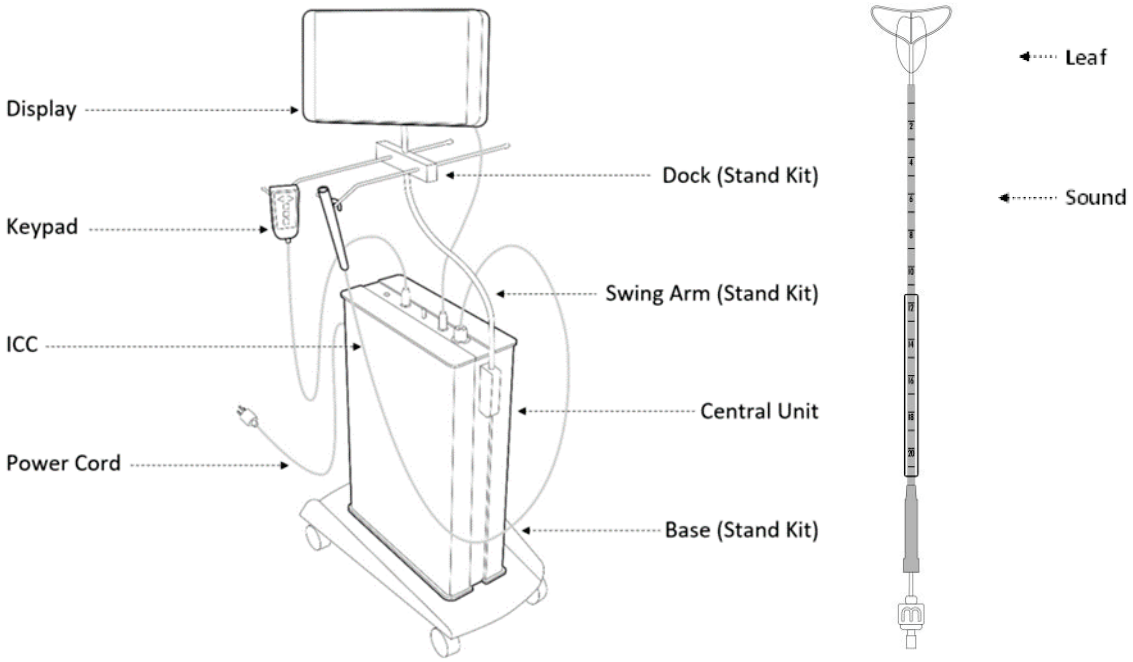
The warnings and precautions can be found in the Minitouch System labeling.

V. DEVICE DESCRIPTION

The Minitouch 3.8 Era System (Minitouch System) is designed and intended for ablation of the endometrial lining of the uterus for the treatment of menorrhagia (heavy menstrual bleeding) due to benign causes in pre-menopausal women for whom childbearing is complete. The Minitouch System creates 3D-shaped energy field using microwave energy to ablate the endometrium, thereby reducing future menstrual bleeding. The procedure involves the clinician inserting a disposable, hand-held Handpiece into the patient's uterus via the cervical canal to enable the delivery of energy to the endometrial tissue via the shaped field. This delivered energy results in controlled destruction of the endometrium to reduce or eliminate bleeding.

The Minitouch System consists of two main components, the Generator and the disposable Minitouch 3.8 Era Handpiece. A diagram of the Minitouch System is provided in **Figure 1**.

Figure 1: Minitouch System



Generator **Handpiece**

The Generator is a non-sterile, reusable 915 MHz microwave energy generator and controller. It generates, monitors, and manages microwave energy delivery to the patient. The user interface of the Generator consists of a Keypad, a Display screen, an audio feedback mechanism to inform the physician of system status, and a Central Unit (CU) with custom connection ports for the Display, Keypad, and Inter-connecting Cable (ICC) which connects to the Handpiece. The Central Unit also has a connection for the power cord. Prior to the energy delivery, the user turns the Generator power on and completes all necessary pre-procedure system checks and settings.

The Handpiece is a sterile, single-use only component that connects to the Generator via an Inter-connecting Cable and delivers energy to the endometrial lining of the uterus via its distal end called the Leaf. The Leaf is retracted into the Sound for insertion and then deployed in the uterine cavity. The Sound is curved at its distal end which is aligned with anteverted/retroverted orientation of the uterus for facilitating insertion and proper placement of the Handpiece into the uterine cavity.

The Handpiece is removed from its sterile package once the patient is prepared for the Minitouch procedure. The preparations include patient pain management and comfort measures, and uterine measurements. The Keypad and Inter-connecting Cable are inserted into the provided sterile covers. The user then connects the Handpiece to the Inter-connecting Cable.

The user then retracts the Leaf into the Sound, inserts the Handpiece into the uterine cavity via the cervical canal, and deploys the Leaf by retracting the Sound. The user

performs a series of steps to verify deployment and position of the Leaf and initiates the main treatment step. At any time, the user can pause and resume the procedure or adjust the power level to optimize patient comfort. If the pre-determined desired treatment length is longer than 4cm, an extension treatment step can be initiated by retracting the HandPiece in increments of up to 2cm or the length not yet treated, whichever is less. Multiple extension treatment steps can be performed until the full desired treatment length is treated.

The user removes the Handpiece from the patient and disposes it and the two covers in accordance with standard precautions or local practice.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several alternatives for the treatment of menorrhagia due to benign causes. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with her physician to select the method that best meets her expectations and lifestyle.

The following alternative practices and procedures are currently available to treat menorrhagia due to benign causes, in the absence of structural abnormalities such as fibroid tumors or polyps:

1. **Drug Therapy**

   Drug therapies, using estrogen-progesterone combinations (such as those found in oral contraceptives) or progesterones (progesterone) by themselves, are approaches frequently employed for the treatment of menorrhagia. Other classes of drugs used include androgens such as Danocrine, gonadotropin-releasing hormone (GnRH) agonists, non-steroidal anti-inflammatory drugs (NSAIDs), and antifibrinolytic medications. Drug therapy is typically the first order of treatment to alleviate heavy menstrual bleeding. Drug therapies usually require long-term treatment. Drug therapy is successful for some women but may be ineffective or cause unpleasant side effects in others. This treatment approach does, however, allow a woman to maintain her fertility.

2. **Dilatation and Curettage (D&C)**

   D&C historically has been the treatment of choice for profuse uterine bleeding in women who are hemodynamically unstable and refractory or intolerant to drug therapy. First the cervix is dilated, and then the endometrial lining of the uterine cavity is either scraped by an instrument or removed/evacuated through vacuum aspiration. D&C may reduce bleeding for a few cycles. If a polyp is present and removed, the bleeding may stop. In most cases, D&C does not provide the patient with long-term definitive results, but may be useful for those women who desire to maintain their fertility.

3. **Hysteroscopic Endometrial Ablation**

Hysteroscopic endometrial ablation is a surgical procedure which utilizes a resectoscope or operating hysteroscope, a video monitor, a fluid distention medium such as Glycine or Sorbitol, and a surgical ablation device such as an electrode loop, rollerball, or laser to destroy the endometrial lining of the uterus. The procedure is typically performed under general or regional anesthesia. The cervix must be dilated to accommodate the hysteroscopic instrument, and the uterine cavity must be properly distended to enable visualization. The most common risks associated with hysteroscopic endometrial ablation are hyponatremia from fluid overload, which is a life-threatening condition, and uterine perforation. This treatment is intended for women who no longer desire fertility.

4. **Second Generation "Global" Endometrial Ablation (GEA)**

Second Generation Global Endometrial Ablation (GEA) technologies are faster, less complex, and, in most cases, allow for a significant reduction in the incidence of complications associated with endometrial ablation, when compared to hysteroscopic endometrial ablation. There are currently eight (8) endometrial ablation systems approved by FDA:

- The ThermaChoice Balloon Endometrial Ablation System (Gynecare, P970021) uses thermal energy from heated sterile fluid (5% dextrose in water) contained within a silastic balloon.
- The HydroTherm Ablation System (Boston Scientific, P000040) uses USP 0.9% saline heated externally and injected into the uterine cavity.
- The Her Option CryoAblation System (Cooper Surgical, P000032) uses cryothermic energy to ablate the endometrium.
- The NovaSure RF Endometrial Ablation System (Hologic, P010013) uses bi-polar RF energy to create heat and destroy the endometrium to a pre-determined depth using tissue impedance.
- The Microsulis Microwave Endometrial Ablation System (Microsulis Medical, P020031) uses microwave energy to heat the endometrial layer using a thermocouple at the tip of the device for ablation depth control.
- The Minerva Endometrial Ablation System (Minerva Surgical, P140013) uses bi-polar RF energy and ionized argon gas to create heat and destroy the endometrium.
- The AEGEA Vapor System™ (AEGEA Medical, P160047) uses heated water vapor to ablate the endometrium.
- The Cerene® Cryotherapy Device (Channel Medsystems, Inc., P180032) uses cryothermic energy to ablate the endometrium.

All of these therapeutic approaches are intended for women who no longer wish to maintain their fertility.

5. **Hysterectomy**

   The most definitive surgical treatment for heavy menstrual bleeding is hysterectomy, or complete removal of the uterus. Hysterectomy is a procedure performed in the hospital (or surgical center) under general anesthesia and is associated with the risks and complications of major surgery. Depending on the technique, hysterectomy may require a lengthy recovery period.

VII. MARKETING HISTORY

The Minitouch System was first issued a CE Mark (CE 558771) on 14 April 2011 and has been marketed since then in the European Union and Great Britain. It has not been marketed in the United States or any other foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of potential adverse effects (e.g., complications) associated with the use of the device.

- Uterine cramping,
- Nausea,
- Vomiting,
- Vasovagal reaction,
- Vaginal discharge, and
- Bleeding or spotting.

For any endometrial ablation procedure, commonly reported postoperative symptoms include the following:

- Postoperative cramping can range from mild to severe. This cramping will typically last a few hours and significantly decrease by the first day following the procedure.
- When present, nausea and vomiting typically occur immediately following the procedure, are associated with anesthesia, and can be managed with medication.
- Vaginal discharge
- Vaginal bleeding/spotting

The following adverse events could occur or have been reported in association with the use of other endometrial ablation systems and may occur when the Minitouch System is used:

- Post-ablation tubal sterilization syndrome
- Pregnancy-related complications (NOTE: pregnancy following endometrial ablation is very dangerous for both the mother and the fetus.)
- Thermal injury to adjacent tissue, including bowel, bladder, cervix, vagina, vulva and/or perineum

- Perforation of the uterine wall
- Cervical or vaginal laceration
- Transient change in appearance of the cervical epithelium
- Mechanical bowel injury
- Diarrhea
- Headache
- Cervical stenosis
- Uterine necrosis
- Hematometra
- Hemorrhage
- Infection or sepsis
- Complications leading to serious injury or death

Some or all of these risks may require a need for reoperation or subsequent treatment and/or may lead to permanent disability or death.

For the specific adverse events that occurred in the clinical study, please see Section X below.

IX. SUMMARY OF NONCLINICAL STUDIES

A. Biocompatibility

The patient contacting components of the Minitouch System include the disposable Handpiece. The Handpiece assembly contacts mucosal membranes for a limited (<24 hour) contact duration. Therefore, in accordance with ISO 10993-1:2009, assessment of the cytotoxicity, sensitization, and irritation potential of these components are needed.

The applicant completed the following biocompatibility testing on the final, finished version of the Handpiece:

- Cytotoxicity - ISO Elution Method (ISO 10993-5:2009)
- Sensitization – Guinea Pig Maximization Test (ISO 10993-10:2010)
- Irritation – Vaginal Irritation Test (ISO 10993-10:2010)

The protocol and results of the above biocompatibility tests are acceptable and demonstrate that the patient contacting components of the Minitouch System are non-cytotoxic, non-sensitizing, and non-irritating.

B. Sterilization Validation

The Minitouch Handpiece is a single-use device. The sterilization method is ethylene oxide (EO). EO process validation results along with bioburden resistance test results support that Minitouch Handpiece has a Sterility Assurance Level of $\leq 10^{-6}$ and complies with ANSI/AAMI/ISO 11135:2014.

The Minitouch Handpiece was adopted into the AAMI TIR28:2009, Product Adoption and Process Equivalence for Ethylene Oxide Sterilization. EO and Ethylene Chlorohydrin (ECH) residual levels met ISO 10993-7:2008 limits for limited exposure type.

Packaging and pouch seal integrity were tested to ensure sterility following shipping and environmental conditioning.

C. Shelf-Life

The Handpiece has a shelf life of one (1) year based on the results of an accelerated aging study. The accelerating study demonstrates that the Handpiece maintains its functionality, and its packaging maintains the sterility of the Handpiece for a shelf life of one (1) year.

The applicant intends to verify the results of the accelerated aging study through a real-time aging study.

D. Mechanical Safety and Performance

The applicant completed design verification and validation testing on the Minitouch System. These tests are outlined below.

Handpiece

- Electrical Functionality – The reflection coefficient and resonant frequency of the antenna were evaluated and found to meet pre-defined design specifications.
- Mechanical Strength – The Handpiece showed no damage and remained functional (energy delivery) after tensile, torsion and anteversion/retroversion forces were applied. These tests verified the ability of the Handpiece to withstand the forces/conditions expected during the procedure.
- Fluid Ingress – The Handpiece was evaluated for functionality (energy delivery) when wet. The Handpiece was found to meet pre-defined design specifications after dipping the antenna in water.
- Deployment – The Handpiece was tested to withstand retraction and deployment representative of clinical use. The Handpiece continued to function (energy delivery) and met pre-defined design specifications.
- Handpiece Markings Verification – Handpiece markings indicating the depth and orientation of the antenna were verified to meet pre-defined design specifications.

Minitouch Generator

- Display Accuracy – The accuracy of the energy and output power values were evaluated and found to meet pre-defined design specifications.
- Audible Signal – The audible signal indicating power delivery was verified and found to meet pre-defined design specifications.
- Generator Output Power – The output frequency, harmonics, and output power of the Generator were measured and found to meet pre-defined design specifications.

- Cleaning – The Generator was tested after cleaning to verify that the Generator remains operational, dielectric strength and leakage current are maintained, and that labels remain adhered and legible. The Generator met pre-defined design specifications after cleaning.
- Packaging/Shipping Verification – The Generator and packaging were subjected to environmental conditioning and simulated distribution. The Generator remained operational and met pre-defined design specifications after simulated shipping.
- Anticipated Shipping Environment – The Generator was evaluated to withstand anticipated shipping pressure and humidity ranges. The Generator remained operational, met pre-defined design specifications, and maintained dielectric strength and leakage current following preconditioning.
- Anticipated Use Environment – The Generator was evaluated to withstand anticipated temperature, pressure, and humidity ranges. The Generator remained operational, met pre-defined design specifications, and maintained dielectric strength and leakage current following preconditioning.
- Expected Storage Conditions – Component analysis of the Generator was used to support the 10-year service life.
- Verification of Generator Design Inputs – The power input, power cord, central unit, and display legibility were evaluated and met pre-defined design specifications.
- Verification of ICC Design Requirements – The insertion loss of the ICC was measured and found to meet pre-defined design specifications.
- Safety of Microwave Therapy Equipment (EN 60601-2-6) – The Minitouch System complies with all applicable subclauses and collateral standards for microwave safety according to IEC 60601-2-6.
- Electromagnetic Compatibility (EN 60601-1-2) – The Minitouch System complies with all applicable subclauses and collateral standards for electromagnetic compatibility according to IEC 60601-1-2.
- Software Verification – The Generator software was tested and verified to meet pre-defined design specifications.
- System Interface Verification – The system interface was verified for start/stop microwave power button functionality and deactivation of power delivery if the ICC is disconnected.

- **System Level Testing (Full Functional Test):** The Minitouch System underwent full functional testing as part of distribution and accelerated aging testing, where devices in the final packaging configuration undergo the full manufacturing, packaging, and sterilization process, as well as temperature exposure, and, in the case of post-distribution functional testing, distribution simulation. The functional testing included verification, validation, and/or qualification that all pre-defined design inputs/specifications were met.

E. Electrical Safety and Electromagnetic Compatibility

The Minitouch System conforms with the following standards related to electrical safety and electromagnetic compatibility:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-2-6: Medical Electrical Equipment - Part 2-6: Particular Requirements for the basic safety and essential performance of microwave therapy equipment
- IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability

F. Software Validation

The applicant provided software information for the Minitouch System in accordance with the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005. The Minitouch System has a major level of concern and the applicant provided documentation of appropriate controls and testing including:

- Level of Concern
- Software Description
- Device Hazard Analysis
- Software Requirements Specifications
- Architecture Design Chart
- Software Design Specification
- Traceability Analysis
- Software Development Environment Description
- Life Cycle Development Plan
- Configuration Management and Maintenance Plan
- Verification and Validation Documentation
- Unit, Integration, and System Level Testing
- Revision Level History
- Unresolved Anomalies
- Cybersecurity Considerations

G. Thermal Modeling

The applicant reported the results of finite element simulation of the thermal performance of the Minitouch System. The applicant completed this testing as part of the initial development of the Minitouch System and compared the results of the simulation to the porcine muscle tissue testing results described in Section H.

H. Porcine Tissue Testing

The applicant conducted *ex vivo* non-perfused porcine muscle tissue testing. Porcine muscle tissue was used to simulate the human uterine cavity. The applicant

conducted ablations for the treatment duration of the Minitouch System at the best-case, realistic case and worst-case energy doses, and then evaluated the ablation depths and widths and lengths of the lesions.

The average ablation depth, as measured from the cavity surface to 0% ablation region, treated with the worst-case energy dose was dependent on the location and ranged from 8.3mm to 14.5mm.

I. Extirpated Uteri Testing

The applicant conducted extirpated uteri testing on the Minitouch System. A total of 47 extirpated uteri procedures were undertaken as part of the early development work on the Minitouch System. The testing evaluated the serosal temperature data post-treatment, histopathological analyses of the extirpated uteri, and device performance.

During these procedures, the applicant evaluated the Minitouch System for uterine integrity, deployment, and ablation parameters. Specifically, the applicant measured uterine serosal temperatures post-ablation and conducted gross and microscopic histological examinations to evaluate thermal tissue effects. The uterine serosal temperatures were found to be within a safe physiological range.

Gross pathology and histological examination on the specimens demonstrated a mean depth of thermal ablation of 4.8mm (2.5mm-7.0mm) in the mid-uterine region, 3.0mm (1.5mm-5.0mm) in the mid-fundal region, 2.6mm (0.0mm-5.0mm) in the lower uterine region, and 3.0mm (2.0mm-5.0mm) in the cornual regions.

Ablation coverage was 96.8% (SD + 6.2%) overall. The maximum global maximum ablation depth was 7.0mm. The applicant did not identify any perforations or signs of serosal thermal injuries. Specifically, the lower endocervix and exocervix did not display any thermal histologic changes.

The test devices were able to deploy and conform to the uterus in all 47 specimens, and the ease of device positioning and removal was acceptable in all procedures.

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

The applicant performed a clinical study, Minitouch Endometrial Ablation System Treatment for Menorrhagia: An Evaluation of Safety and Effectiveness (EASE Clinical Trial), to establish a reasonable assurance of safety and effectiveness of endometrial ablation with the Minitouch System for its labeled indication, endometrial ablation in premenopausal women with heavy menstrual bleeding due to benign causes for whom childbearing is complete, in the US under IDE # G180282. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between August 2020 and December 2020. The database for this PMA reflected data collected through one-year (12-months) post-procedure and included 114 patients. There were five (5) investigational sites.

The study was a prospective, single-arm, non-randomized, multicenter, open label clinical study. The purpose of the clinical trial was to evaluate the safety and effectiveness of the use of the Minitouch System in premenopausal women suffering from menorrhagia due to benign causes. Follow-up visits occurred at 24-hours, 2 weeks, 3-months, 6-months, and 12-months post-procedure.

The primary safety endpoint was occurrence of adverse events. The applicant evaluated safety by determining the number and percentage of subjects who experienced one or more adverse events, and the number of subjects who experienced device-related serious adverse events (SAEs) during the clinical investigation.

The primary effectiveness endpoint was menstrual blood loss as assessed by the Pictorial Blood Loss Assessment Chart (PBLAC) method. This is a validated menstrual diary scoring system developed by Higham (Higham JM, O'Brien PMS, Shaw RW Br J Obstet Gynaecol 1990; 97:734-9). An individual patient was considered a success if her PBLAC score was ≤ 75 at 12 months post-treatment without incidence of acute treatment failure or additional therapy during follow-up to control menorrhagia.

The secondary outcome measures included: amenorrhea rates, improvement in quality of life measures, patient and investigator satisfaction with the treatment, and need for medical or surgical intervention to treat menorrhagia (heavy menstrual bleeding), procedure related parameters, and incidence of adverse events (including serious and unanticipated adverse device effects).

The analysis population was the Intent-to-Treat (ITT) population (i.e., all subjects who presented and in whom the Minitouch procedure was initiated).

The effectiveness of the Minitouch System was compared to an FDA established objective performance criterion (OPC). The OPC was developed with input from industry and members of the Obstetrics and Gynecology Devices Panel. The OPC approach utilized data from the pivotal clinical trials of the five approved endometrial ablation systems. These fives studies were randomized, controlled trials that used the same active control (rollerball ablation) and had similar patient populations. The study sizes ranged from 260 patients to 322 patients with either a 1:1 randomization or a 2:1 (device: control) randomization scheme. The primary endpoint was reduction in menstrual blood loss as assessed by PBLAC. The inclusion criteria required either a baseline PBLAC score of > 150 (four studies) or > 185 (one study), and individual patient success was defined as a PBLAC score of ≤ 75 at 12 months post procedure. The ITT population consisted of all patients who presented on the

day for either the endometrial ablation device or rollerball ablation. Patients with missing PBLAC scores at 12-months were treated as failures. A study was considered a success, if the proportion of successes in the GEA group met a pre-specified non-inferiority margin compared to the proportion of successes in the rollerball ablation control group.

Using a generalized linear mixed model with study as a random effect, the FDA determined that the average success rate across the five GEA devices was 75.6% (65.6%, 83.5%) and 77.2% (66.5%, 85.2%) for the rollerball ablation control. The FDA performed additional analyses to evaluate the effect of baseline covariates on the primary endpoint, including age (above and below 40), baseline PBLAC score (over 150), uterine sound (6 to 12 centimeters), and presence of fibroids (< 3 cm). Using analysis of covariance methods, the FDA found that none of these baseline covariates had a significant impact on the study results. Based on this analysis, the FDA developed a minimum success rate for effectiveness known as an objective performance criterion (OPC). The OPC is 66% based on the lower bound of the 95% confidence interval of the average success rate for the five approved GEA devices.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the single-arm study was limited to patients who met the following inclusion criteria:

   - Female age 30 to 50 years
   - Excessive menstrual bleeding due to benign causes
   - Uterine sounding depth measurement of 6.0 – 12.0 cm (external os to internal fundus)
   - A minimum uterine cavity length of 4.0 cm (internal os to internal fundus)
   - A minimum PBLAC score of ≥ 150 for 1 menstrual cycle (obtained during screening) and must also have a documented history of excessive menstrual bleeding prior to study enrollment
   - Endometrial biopsy within 12 months prior to treatment procedure with no abnormal pathology
   - Premenopausal at screening as determined by FSH measurement ≤ 40 IU/L when age is ≥ 40 years
   - Patient agrees to use a reliable form of contraception during the study, and to follow these requirements:
     - If a hormonal birth control method is used for contraception, the patient must have been on said method for ≥ 3 months prior to the onset of the screening menstrual cycle and agrees to remain on the same hormonal regimen through the initial 12-month post-treatment follow-up (pills, injections, patches, rings, implants)
     - Patient also agrees to not use hormonal birth control during the first 12-month post-treatment follow-up period if they were not using hormonal birth control during the 3 months prior to treatment
   - Ability to provide written informed consent

- Patient is literate and clearly demonstrates understanding on how to use PBLAC after training
- Patient agrees to the following during the study:
  - No initiation of hormonal contraception or any other medical intervention for bleeding
  - Attend all follow-up exams through the 36-month follow-up timepoint
  - Exclusive use of study-provided sanitary products and submission of completed PBLAC diaries through the 12-month post-treatment follow-up

Patients were not permitted to enroll in the single-arm study if they met any of the following exclusion criteria:

- Pregnant, or desires to retain fertility
- Current or documented history of endometrial hyperplasia
- Active endometritis
- Clinically significant or suspected adenomyosis indicated by patient complaints, imaging, or clinician's judgment
- Active infection of the genitals, vagina, cervix, uterus, adnexa, or urinary tract
- Active pelvic inflammatory disease
- Currently using an intrauterine device (IUD), including Mirena™ device, and unwilling to remove the IUD
- Presence of an implantable contraceptive device (e.g., Essure®) protruding into the uterine cavity
- Active sexually transmitted disease (STD) at the time of ablation
- Presence of bacteremia, sepsis, or other active systemic infection
- Currently on anticoagulants
- Known clotting defects or bleeding disorders
- Currently on medications that could thin the myometrium, such as long-term steroid use (except inhaler or nasal therapy for asthma or other pulmonary condition)
- Previous medical/surgical treatments, or has other conditions, that could lead to anatomic/pathologic weakness or thinning of the myometrium (Classical caesarean section and transmural myomectomy are examples of such treatments that may interrupt the integrity of the uterine wall)
- Any general health, mental health or social situation which, in the opinion of the investigator, could represent an increased risk for the patient, or the ability of the patient to complete study requirements
- Known/suspected abnormal uterine/pelvic anatomy or condition, such as frozen pelvis
- Abdominal, pelvic or gynecological malignancy
- Untreated/unevaluated cervical dysplasia, except cervical intraepithelial neoplasia I (CIN I)
- Previous endometrial ablation procedure

- Abnormal or obstructed, or perforated cavity as determined by investigator via standard clinical practices (e.g., hysteroscopy, saline infusion sonohysterography). This includes, but is not limited to:
  - Septate or bicornuate uterus, arcuate uterus or other congenital malformation of the uterine cavity
  - Pedunculated or submucosal myomas distorting the uterine cavity or not fully resected
  - Polyps larger than 1 cm
- Intramural or subserosal myomas > 3 cm in size, or any myoma that distorts the uterine cavity
- Any patient who is currently participating or considering participation in any other research of an investigational drug or device

Endometrial pretreatment (e.g., hormone, dilation and curettage) or period timing was not used in the trial.

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 24-hours, 2 weeks, 3-months, 6-months and 12-months postoperatively.

Preoperatively, each subject completed a self-reported PBLAC diary to record menstrual bleeding. These diaries were scored by a contract research organization (CRO) via the Electronic Database Capturing (EDC) to ensure the subject had a minimum PBLAC score of ≥ 150 for inclusion in the Trial. The subjects also completed the validated Menstrual Impact Questionnaire (MIQ), Dysmenorrhea-related Numerical Rating Scale (NRS) and Procedure-related Pain NRS at baseline prior to undergoing the Minitouch procedure.

Postoperatively, each subject maintained monthly self-reported PBLAC diaries starting at month one (M1) to a minimum of 365 days post-ablation (the primary endpoint PBLAC captures data through 365 days). Subjects completed the MIQ, Dysmenorrhea NRS, patient satisfaction with the treatment (also known as the Patient Global Evaluation (PGE)) at 3, 6 and 12-months post-procedure. Subjects completed the Procedure-related Pain NRS at discharge and at the 24-hour contact. Investigators completed the investigator satisfaction with the treatment questionnaire (also known as the Investigator Global Evaluation (IGE)) at 3, 6 and 12-months. The MIQ, Dysmenorrhea NRS, PGE and IGE will also be assessed at the 24 and 36-month follow-ups. Adverse events and complications were recorded at all visits.

The key timepoints are shown below in the tables summarizing safety and effectiveness.

3. Clinical Endpoints

With regard to safety, the primary safety endpoint was occurrence of adverse events. The applicant evaluated safety by determining the number and percentage

of subjects who experienced one or more adverse events and the number of subjects who experienced device-related serious adverse events (SAEs).

With regard to effectiveness, the primary effectiveness endpoint was menstrual blood loss as assessed by the Pictorial Blood Loss Assessment Chart (PBLAC) method. An individual subject was considered a success if her PBLAC score was ≤ 75 at 12 months post-treatment without incidence of acute treatment failure or additional therapy during follow-up to control menorrhagia.

With regard to success/failure criteria, to achieve study success, the lower bound of the 95% confidence interval should exceed the 66% OPC developed by the FDA.

The secondary endpoints included procedure related parameters, amenorrhea rates, MIQ, Dysmenorrhea NRS, PGE and IGE.

B. Accountability of PMA Cohort

At the time of database lock, of 114 patients enrolled in the PMA study, 100% (114) patients are available for analysis at the 12-month post-operative visit. **Table 1** summarizes subject disposition.

Table 1: Subject Disposition at Month 12

Disposition Category	Safety % (N)	Effectiveness % (N)
ITT: Treated	100% (114)	100% (114)
Subjects with a known Month 12 outcome	100% (114)	100% (114)

C. Study Population Demographics and Baseline Parameters

The demographics of the ITT cohort are typical for an endometrial ablation trial performed in the United States. **Table 2** and **Table 3** provide the baseline demographic and obstetrical/gynecological history parameters.

Thirty four (34) subjects were 30-40 years old, and 80 subjects were >40 years old. The mean age of subjects at baseline was 41.8 years. The mean PBLAC score was 264.9 (SD 161.39) and ranged between 151.5 to 1070. An evaluation of these data confirmed the data could be pooled across sites.

Table 2: Baseline Demographics and Obstetric History
ITT Analysis Cohort

	N = 114
Age (years) [1]	
Mean ± SD (N)	41.8 ± 4.66 (114)
Median (Min, Max)	42.0 (30.0, 50.0)
Ethnicity	
Hispanic or Latino	12.3% (14/114)

Table 2: Baseline Demographics and Obstetric History
ITT Analysis Cohort

	N = 114
Not Hispanic or Latino	87.7% (100/114)
Race [2]	
American Indian or Alaska Native	0.0% (0/114)
Asian	1.8% (2/114)
Black or African American	2.6% (3/114)
Native Hawaiian or Other Pacific Islander	0.0% (0/114)
White	94.7% (108/114)
Other	1.8% (2/114)
BMI (kg/m2)	
Mean ± SD (N)	29.7 ± 6.24 (114)
Median (Min, Max)	28.9 (17.8, 50.3)
Obstetric History	
Prior Pregnancies	94.7% (108/114)
Gravida [3]	
Mean ± SD (N)	2.9 ± 1.2 (108)
Median (Min, Max)	3.0 (1.0, 6.0)
Para [3]	
Mean ± SD (N)	2.4 ± 1.0 (108)
Median (Min, Max)	2.0 (0.0, 5.0)
Full-Term Deliveries [3]	
Mean ± SD (N)	2.3 ± 1.1 (108)
Median (Min, Max)	2.0 (0.0, 5.0)
Previous Cesarean Section (Low Transverse) [4]	
Mean ± SD (N)	1.7 ± 0.8 (43)
Median (Min, Max)	2.0 (1.0, 5.0)
PBLAC Score at Baseline	
Mean ± SD (N)	264.9 ± 161.39 (114)
Median (Min, Max)	204.1 (151.5, 1070.0)

[1] Age is calculated on day of procedure.
[2] Subjects could report more than one race so numbers may be greater than the total.
[3] Gravida, Para, and Full-Term Deliveries are calculated among subjects with prior pregnancies.
[4] Previous Cesarean Section (Low Transverse) are calculated only among those who have undergone at least one Cesarean Section (Low Transverse).

Table 3: FSH Measurement

FSH (IU/L) **(subjects >40 years of age at screening)**	**N = 75**
Mean ± SD (N)	7.3 ± 5.74 (75)
Median (Min, Max)	6.2 (0.6, 35.9)

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the ITT cohort of 114 subjects available for the 12-month evaluation. The key safety outcomes for this clinical trial are presented in **Table 4**.

Table 4 shows the number and percent of women who reported specific endometrial ablation-related adverse events and symptoms (one or more times) during the 12-month follow-up period. These device or procedure related adverse events were considered non-serious.

There were no reported device or procedure related serious adverse events.

Table 4: Device or procedure related non-serious adverse events.

N = 114	Day 0	Day 1	Day 2 to Week 2	Week 3 to Month 12
Abdominal	0.9% (1/114)		0.9% (1/114)	
Bacterial Vaginosis			0.9% (1/114)	0.9% (1/114)
Chills	1.8% (2/114)			
Dizziness	0.9% (1/114)			
Hot Flash	0.9% (1/114)			
Pollakiuria	0.9% (1/114)			
Presyncope	0.9% (1/114)			
Procedural Nausea	5.3% (6/114)			
Procedural Pain	1.8% (2/114)			0.9% (1/114)
Procedural	4.4% (5/114)			
Somnolence	0.9% (1/114)			
Uterine Pain	1.8% (2/114)			
Uterine Spasm	38.6% (44/114)	1.8% (2/114)	2.6% (3/114)	0.9% (1/114)
Vaginal Discharge	1.8% (2/114)		0.9% (1/114)	
Vaginal Odor			0.9% (1/114)	
No. of Events	69	2	7	3
No. of Subjects	48	2	7	3
% of Subjects	43.0%	1.8%	6.1%	2.6%

2. Effectiveness Results

The analysis of effectiveness was based on the 114 evaluable subjects at the 12-month time point. Key effectiveness outcomes are presented in **Tables 5** to **10**.

Based on the success rate of 89.5% with a 95% confidence interval (CI) (82.3, 94.4) observed in the ITT population, the null hypothesis was rejected at the significance level of 5%, and the 12-month follow-up success rate observed with the Minitouch System was demonstrated to be statistically significantly greater

than the OPC of 66% (p-value <0.001). The primary endpoint of effectiveness was met in the ITT population.

Table 5 summarizes the effectiveness outcomes from the single arm clinical trial.

Table 5: Effectiveness Outcomes at Month 12

	% or n N=114
Number of successes (PBLAC score ≤75)	102
Trial success rate (% subjects with PBLAC score ≤75)	89.5% (82.3%, 94.4%)
p-value	<0.001
Number of subjects reporting amenorrhea (PBLAC score=0)	59
Amenorrhea rate (% subjects with PBLAC score=0)	51.8%
Note: One sided p-value = 0.0000000066	

Table 6 summarizes the dysmenorrhea numerical rating scale (NRS) results from the single arm clinical trial. The subjects were asked at baseline if they experienced dysmenorrhea. The subjects who reported symptoms at baseline experienced a reduction of symptoms at Month 12.

Table 6: Dysmenorrhea NRS Through 12 Months Post-Procedure

	Baseline (N=114)	**Month 12 (N=114)**
Subject Report Dysmenorrhea NRS Score		
Mean ± SD (N)	6.1 ± 2.6 (114)	0.83 ± 1.5 (114)
Median (Min, Max)	7.0 (1.0, 10.0)	0.0 (0.0, 6.0)
Mode	5.0	0.0
Score Distribution		
0 = no symptom	4.4% (5/114)	66.7% (76/114)
1	4.4% (5/114)	10.5% (12/114)
2	4.4% (5/114)	9.6% (11/114)
3	3.5% (4/114)	5.3% (6/114)
4	1.8% (2/114)	3.5% (4/114)
5 = moderate	17.5% (20/114)	2.6% (3/114)
6	13.2% (15/114)	1.8% (2/114)
7	16.7% (19/114)	0.0% (0/114)
8	14.0% (16/114)	0.0% (0/114)
9	16.7% (19/114)	0.0% (0/114)
10 = worst pain possible	3.5% (4/114)	0.0% (0/114)
Missing	0.0% (0/0)	0.0% (0/0)
Percent of Subjects with Reduction in Dysmenorrhea NRS Score		93.9% (107/114)
Dysmenorrhea NRS Scores by Change Category		
Reduced [93.9% (107/114)]		
Mean ± SD (N)	6.4 ± 2.3 (107)	0.7 ± 1.4 (107)
Median (Min, Max)	7.0 (1.0, 10.0)	0.0 (0.0, 6.0)

Mode	5.0	0.0
Same (No Change) [2.6% (3/114)]		
Mean ± SD (N)	0.7 ± 1.2 (3)	0.7 ± 1.2 (3)
Median (Min, Max)	0.0 (0.0, 2.0)	0.0 (0.0, 2.0)
Mode	0.0	0.0
Increased [3.5% (4/114)]		
Mean ± SD (N)	1.3 ± 2.5 (4)	3.3 ± 1.9 (4)
Median (Min, Max)	0.0 (0.0, 5.0)	2.5 (2.0, 6.0)
Mode	0.0	2.0
Note: The ITT and PP analysis cohorts are the same.		

Table 7 summarizes the patient satisfaction responses for the Menstrual Impact Questionnaire (MIQ) at baseline and Month 12.

Table 7: MIQ through 12 Months Post-Procedure

Menorrhagia Impact Questionnaire (MIQ)	**Baseline N = 114**	**Month 12 N = 114**
MIQ 1: Perception of Amount of Blood Loss		
None	0.0% (0/114)	41.2% (47/114)
Spotting	0.0% (0/114)	12.3% (14/114)
Light	0.9% (1/114)	25.4% (29/114)
Moderate	3.5% (4/114)	15.8% (18/114)
Heavy	34.2% (39/114)	3.5% (4/114)
Very Heavy	61.4% (70/114)	1.8% (2/114)
MIQ 2: Limitations in Work Outside or Inside the Home		
Not at all	7.9% (9/114)	94.7% (108/114)
Slightly	14.9% (17/114)	2.6% (3/114)
Moderately	29.8% (34/114)	2.6% (3/114)
Quite a bit	29.8% (34/114)	0.0% (0/114)
Extremely	17.5% (20/114)	0.0% (0/114)
MIQ 3: Limitations in Physical Activity		
Not at all	1.8% (2/114)	93.0% (106/114)
Slightly	17.5% (20/114)	4.4% (5/114)
Moderately	23.7% (27/114)	1.8% (2/114)
Quite a bit	35.1% (40/114)	0.9% (1/114)
Extremely	21.9% (25/114)	0.0% (0/114)
MIQ 4: Limitations in Social or Leisure Activities		
Not at all	6.1% (7/114)	94.7% (108/114)
Slightly	17.5% (20/114)	3.5% (4/114)
Moderately	26.3% (30/114)	0.9% (1/114)
Quite a bit	31.6% (36/114)	0.9% (1/114)
Extremely	18.4% (21/114)	0.0% (0/114)
MIQ 5: Activities that were Limited by Excessive Bleeding [1]		
None	5.3% (6/114)	91.2% (104/114)
Access to Bathroom	14.9% (17/114)	0.9% (1/114)

Menorrhagia Impact Questionnaire (MIQ)	Baseline N = 114	Month 12 N = 114
Exercise/Physical Activity	58.8% (67/114)	4.4% (5/114)
School	0.9% (1/114)	0.0% (0/114)
Sex	6.1% (7/114)	0.0% (0/114)
Sitting	3.5% (4/114)	0.0% (0/114)
Sleeping	10.5% (12/114)	0.9% (1/114)
Socializing	25.4% (29/114)	3.5% (4/114)
Swimming	22.8% (26/114)	0.9% (1/114)
Work	19.3% (22/114)	0.0% (0/114)
Other	13.2% (15/114)	0.9% (1/114)
MIQ 6: Global Assessment of Change in Blood Loss		
About the same	N/A	1.8% (2/114)
Better	N/A	98.2% (112/114)
Meaningful Change	N/A	94.6% (106/112)
Worse	N/A	0.0% (0/114)
Meaningful Change	N/A	0.0% (0/0)
[1] Subjects could report more than one activity so numbers may be greater than the total. Note: The ITT and PP analysis cohorts are the same.		

Table 8 summarizes the patient global evaluation (PGE) for patient satisfaction with the treatment received.

Table 8: Patient Global Evaluation (PGE) with Treatment Through 12 Months Post-Procedure

	N = 114
Patient Satisfaction with Treatment	
Very Satisfied	76.3% (87/114)
Satisfied	14.9% (17/114)
Not Sure	2.6% (3/114)
Dissatisfied	4.4% (5/114)
Very Dissatisfied	1.8% (2/114)
Recommend to Friends	
Yes	93.9% (107/114)
No	6.1% (7/114) [1]
Note: The ITT and PP analysis cohorts are the same. [1] Two (2) subjects with primary endpoint PBLAC scores that met the success criterion replied “No” to this question. Subject 04-028’s primary endpoint PBLAC score = 0, however, the subject would not recommend the procedure because she felt it was painful. Subject 05-027’s primary endpoint PBLAC score = 11.5, however, the subject responded "No" to this question for the following reasons: (1) although her periods are much lighter, her expectations were to have no bleeding at all, and (2) she described her experience with the procedure as extremely painful.	

Table 9 summarizes the investigator global evaluation (IGE) for investigator satisfaction with the treatment.

Table 9: Investigator Global Evaluation (IGE) Through 12 Months Post-Procedure

	N = 114
Investigator Satisfaction with Treatment	
Very Satisfied	70.2% (80/114)
Satisfied	24.6% (28/114)
Not Sure	1.8% (2/114)
Dissatisfied	2.6% (3/114)
Very Dissatisfied	0.9% (1/114)
Note: The ITT and PP analysis cohorts are the same.	

Table 10 summarizes the procedure-related pain numerical rating scale (NRS) scores.

Table 10: Procedure-Related Pain Numerical Rating Scale (NRS) Score

	N = 114
Pre-Procedure	
Mean ± SD (N)	0.6 ± 1.5 (114)
Median (Min, Max)	0.0 (0.0, 7.0)
Mode	0
Score Distribution	
0 = No Pain	77.2% (88/114)
1	7.0% (8/114)
2	6.1% (7/114)
3	3.5% (4/114)
4	1.8% (2/114)
5 = Moderate Pain	0.9% (1/114)
6	2.6% (3/114)
7	0.9% (1/114)
8	0.0% (0/114)
9	0.0% (0/114)
10 = Worst Pain Possible	0.0% (0/114)
Discharge	
Mean ± SD (N)	2.6 ± 2.4 (114)
Median (Min, Max)	2.0 (0.0, 10.0)
Mode	0
Score Distribution	
0 = No Pain	21.1% (24/114)
1	17.5% (20/114)
2	20.2% (23/114)
3	14.0% (16/114)
4	6.1% (7/114)
5 = Moderate Pain	8.8% (10/114)
6	4.4% (5/114)
7	2.6% (3/114)
8	1.8% (2/114)

9	0.9% (1/114)
10 = Worst Pain Possible	2.6% (3/114)
24-Hours Post-Procedure	
Mean ± SD (N)	1.2 ± 1.5 (114)
Median (Min, Max)	1.0 (0.0, 6.0)
Mode	0
Score Distribution	
0 = No Pain	44.7% (51/114)
1	23.7% (27/114)
2	14.9% (17/114)
3	7.9% (9/114)
4	3.5% (4/114)
5 = Moderate Pain	3.5% (4/114)
6	1.8% (2/114)
7	0.0% (0/114)
8	0.0% (0/114)
9	0.0% (0/114)
10 = Worst Pain Possible	0.0% (0/114)
Note: The ITT and PP analysis cohorts are the same.	

3. Procedure Details

Procedure details for the ITT analysis cohort were collected and are summarized in **Table 11**.

Table 11: Procedure Details ITT Analysis Cohort

	N=114
Completed Procedure	100.0% (114/114)
Total Procedure Time (mins; device insertion to device removal)	
Mean ± SD (N)	7.0 ± 2.12 (114)
Median (Min, Max)	7.0 (4.0, 16.0)
Total Treatment Time (sec; total energy delivery time)	
Mean ± SD (N)	219.9 ± 36.45 (114)
Median (Min, Max)	218.0 (142.0, 341.0)
Total Procedure Energy Delivered (Joules)	
Mean ± SD (N)	5768.4 ± 719.18 (114)
Median (Min, Max)	6000.0 (3000.0, 7200.0)
Power Settings for Main Treatment (W)	
Mean ± SD (N)	35.0 ± 2.35 (114)
Median (Min, Max)	36.0 (30.0, 40.0)
Power Settings for Extension Treatment (W)	
Mean ± SD (N)	35.0 ± 2.44 (103)
Median (Min, Max)	36.0 (30.0, 40.0)
Desired Treatment Length (cm)	
Mean ± SD (N)	5.2 ± 0.83 (114)
Median (Min, Max)	5.0 (4.0, 7.0)

Table 11: Procedure Details ITT Analysis Cohort

	N=114
Setting	
Physician's office	100.0% (114/114)
Outpatient Clinic/Facility (Surgery Center)	0.0% (0/114)
Affiliated Hospital	0.0% (0/114)
Other	0.0% (0/114)
Pain Management Regimen	
Analgesics only	9.6% (11/114)
Anesthesia only	7.0% (8/114)
Conscious (IV) Sedation	0.0% (0/8)
General	100.0% (8/8)
Local	0.0% (0/8)
Multiple	0.0% (0/8)
Both Analgesics and Anesthesia	83.3% (95/114)
Conscious (IV) Sedation + Analgesics	0.0% (0/95)
General + Analgesics	0.0% (0/95)
Local + Analgesics	72.6% (69/95)
Multiple + Analgesics [1]	27.4% (26/95)
Cervical Dilation Required	
Yes	7.9% (9/114)
No	92.1% (105/114)
Active Bleeding at Time of Procedure	
Yes	24.6% (28/114)
No	75.4% (86/114)
Sounding Depth S1	
Mean ± SD (N)	8.6 ± 1.05 (114)
Median (Min, Max)	8.5 (7.0, 11.0)
Sounding Depth S2	
Mean ± SD (N)	8.6 ± 1.09 (114)
Median (Min, Max)	8.5 (7.0, 11.5)
Sounding Depth S3	
Mean ± SD (N)	8.6 ± 1.11 (114)
Median (Min, Max)	8.0 (7.0, 11.5)
Recovery Location	
Waiting Room	0.0% (0/114)
Recovery Room	90.4% (103/114)
Procedure Room	5.3% (6/114)
Other	4.4% (5/114)
Recovery Time (min)	
Mean ± SD (N)	20.8 ± 22.70 (114)
Median (Min, Max)	13.0 (5.0, 177.0)
[1] Multiple indicates both conscious (IV) sedation and local anesthesia were used.	

4. Subgroup Analyses

The following preoperative characteristics were evaluated for potential association with outcomes: baseline PBLAC score. On average, the baseline PLBAC scores for subjects in this study were lower and did not include subject with very high scores compared to other GEA device studies. Safety and effectiveness outcomes of the top 50% (57/114) of the subjects with the highest baseline PBLAC score were analyzed to determine whether the mean baseline PBLAC scores affected the study outcome.

The baseline PBLAC scores and safety and effectiveness outcomes for the top 50% of subjects with the highest baseline PBLAC score and all subjects (114/114) are presented in **Tables 12** to **14**.

Table 12: Baseline PBLAC scores for the study population and top 50% of subjects with the highest baseline PBLAC score.

		Baseline PBLAC Score		
Subject Cohort	**N**	**Mean**	**Min**	**Max**
100%	114	264.9	151.5	1070.0
Top 50%	57	359.1	205.0	1070.0

Table 13: Effectiveness outcomes of the top 50% (57/114) of the subjects with the highest baseline PBLAC scores.

Subject Cohort	**N**	**Mean Baseline PBLAC**	**Treatment Success**	**Amenorrhea Rate**
100%	114	264.9	89.5% (102/114)	51.8% (59/114)
Top 50%	57	359.1	82.5% (47/57)	54.4% (31/57)

Table 14: Safety outcomes of the top 50% (57/114) of the subjects with the highest baseline PBLAC scores.

Subject Cohort	**N**	**Mean Baseline PBLAC**	**SAE - 12 Months**
100%	114	264.9	0
Top 50%	57	359.1	0

The safety and effectiveness outcomes of the top 50% of subjects with the highest baseline PBLAC scores were consistent with the overall study population.

5. Pediatric Extrapolation

In this premarket application, existing clinical data were not leveraged to support approval of a pediatric population.

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included five investigators. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of Section 515(c)(2) of the Food, Drug and Cosmetic Act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Obstetrics and Gynecology Devices Panel, an FDA advisory committee, for review and recommendation, because the information in the PMA substantially duplicates information previously reviewed by this panel.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

In the single arm clinical trial, the observed success rate in the ITT analysis cohort was 89.5% with a 95% confidence interval (CI) of (82.3%, 94.4%) at 12 months. The lower bound of the 95% CI (82.3%) exceeds the objective performance goal of a 66% success rate. The primary endpoint of effectiveness was met in the ITT analysis cohort.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory studies as well as data collected in a clinical study conducted to support PMA approval as described above. The safety profile for the subject device is favorable based on the 12-month outcomes from the study. Most of the adverse events occurred within 30 days of the procedure and resolved without clinical sequelae. The most common adverse events included pelvic cramping, vaginal discharge, and anesthesia related events.

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The benefit of the Minitouch System is reduction in menstrual blood loss. At 12-months, 89.5% (102/114) of treated subjects met the trial definition of success and experienced a reduction in

menstrual blood loss from heavy to normal or less than normal. Based upon available clinical performance outcomes, the risks associated with the Minitouch procedure are modest and similar to risks associated with approved global endometrial ablation systems.

Additional factors to be considered in determining probable risks and benefits for the Minitouch System include:

1. The clinical trial demonstrated that treatment with the Minitouch System does not necessitate the use of IV sedation or general anesthesia and can be performed in an office setting.

2. Patient Perspectives considered during the review included:

    - Quality of Life (Menorrhagia Impact Questionnaire and Dysmenorrhea-related Numerical Rating Scale (NRS) Pain Score)
    - Subject Satisfaction (level of satisfaction with their outcome following treatment and whether they would recommend the treatment to family/friends)

In conclusion, given the available information above, the data support that for ablation of the endometrial lining of the uterus in pre-menopausal women with menorrhagia (heavy menstrual bleeding) due to benign causes for whom childbearing is complete, the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use and also support that the probable benefits outweigh the probable risks for the Minitouch System.

The applicant is in process of obtaining long-term (two and three-year) safety and effectiveness data from subjects in the ITT cohort of the EASE Clinical Trial. Two and three-year safety and effectiveness outcomes will be collected post-market for these subjects. The labeling for the Minitouch System will be revised with this information when it becomes available.

The reported clinical outcomes from the EASE Clinical Trial and the long-term follow-up plan are adequate for premarket approval.

XIII. CDRH DECISION

CDRH issued an approval order on July 28, 2023. The final clinical conditions of approval cited in the approval order are described below.

The applicant must complete a post-approval study (PAS) within two years of approval. At least 85% of the current patient cohort must be followed out to 36 months post procedure. The applicant must provide the following data in post-approval study (PAS) reports for each PAS listed below:

EASE Clinical Trial – The EASE Clinical Trial is a prospective, single-arm, non-randomized, multicenter, open label study conducted at five (5) sites in the United States to evaluate the safety and effectiveness of the Minitouch System. The study includes 114 pre-menopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete. The one-year outcome data from this study were reviewed and used to support PMA approval. The two- and three-year outcomes from this study will be provided post-market and will consist of the following:

- Need for surgical or medical intervention to treat abnormal bleeding
- Subject self-report of pregnancy
- Contraception status (data to be collected at 3 years only)
- Menstrual status
- Gynecologic adverse events
- Quality of Life Questionnaire
- Patient Satisfaction

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.