

**DE NOVO CLASSIFICATION REQUEST FOR
THE CABOCHON SYSTEM**

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Powered surgical instrument for improvement in the appearance of cellulite. A powered surgical instrument for improvement in the appearance of cellulite is a prescription device that is used for the controlled release of subcutaneous tissue for improvement in the appearance of cellulite. The device consists of a cutting tool powered by a motor and a means for instrument guidance to control the areas of subcutaneous tissue cutting underneath the cellulite depressions or dimples.

NEW REGULATION NUMBER: 878.4790

CLASSIFICATION: II

PRODUCT CODE: OUP

BACKGROUND

DEVICE NAME: Cabochon System

SUBMISSION NUMBER: K101231

DATE OF DE NOVO: October 29, 2011 (Received October 31, 2011)

CONTACT:

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REQUESTER'S RECOMMENDED CLASSIFICATION: II

INTENDED USE

The Cabochon System is intended for improvement in the appearance of cellulite.

INDICATIONS FOR USE

The Cabochon System is intended for the short-term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females.

LIMITATIONS

The sale, distribution, and use of the Cabochon System are restricted to prescription use only.

Limitations on device use are also achieved through the following statements included in the Instructions for Use:

“The safety and effectiveness of more than one treatment with the Cabochon System has not been established.”

The safety and effectiveness of the Cabochon System has been evaluated in the buttocks and thighs of adult females between the ages of 25 and 55, with a body mass index (BMI) between 18 and 35, and with moderate to severe cellulite. Safety and effectiveness in other anatomical areas or in patients outside of these criteria has not been established.”

“Failure to carefully follow all applicable instructions may result in injury to the patient, physician, or attendants and may have an adverse effect on procedural outcomes.”

“The sterile products provided as part of the Cabochon System are for single use only. Do not re-use or re-sterilize. Resterilization of the device or components may result in a risk of device malfunction and/or contamination due to residual fluids/tissue in the device.”

“The Cabochon System should be used with a commercially available suction pump with footswitch attachment and accessory suction tubing/isolation canister. The negative pressure from the suction pump is used only with the Vacuum Handpiece for the acquisition of the tissue and there is no active fluid removal or subcutaneous use of vacuum pressure. The suction pump should have adjustable pressure with an accurate gauge (+/- 10%), be rated for a differential negative pressure of 60 kPa and 30 liters per minute of flow. The connector from the suction tubing to the Vacuum Handpiece of the Cabochon System is a 1/4” barb.”

Please refer to the labeling for a more complete list of warnings, precautions, and contraindications.

DEVICE DESCRIPTION

The Cabochon System temporarily improves the appearance of cellulite by controlled release (cutting) of the subcutaneous tissue underneath the cellulite depressions or dimples. The release of subcutaneous tissue for improvement in the appearance of cellulite is a surgical technique

currently performed by physicians using a variety of manual surgical instruments. The depth and specific area of release achieved with the manual surgical instruments are generally variable and user-dependent. The Cabochon System has been designed to provide added control over both the depth and area of release.

System Overview

The Cabochon System consists of a sterile Disposable Kit and a reusable Motor Module which are illustrated in Figure 1. A sterile Vacuum Handpiece assembly controls the depth of treatment with associated Guidance Platforms that define the treated area. The Vacuum Handpiece is used with a commercially available, electrically powered suction pump to draw the tissue up into the recess only. There is no active suction of fluid or application of negative pressure to the subcutaneous space. The specifications for the suction pump are provided in the Cabochon System labeling. A sterile Anesthesia Needle assembly is used to facilitate subcutaneous, physician prescribed anesthetic infiltration prior to treatment. The tissue release is accomplished through the mechanical action of a single use, sterile Release Blade. The Release Blade assembly (Figure 2) is attached to the reusable Motor Module (Figure 3) that is moved by the user through a defined path in the Guidance Platform. Through the use of interchangeable Guidance Platforms the same Vacuum Handpiece can be used for anesthesia needle guidance and several different subcutaneous release areas. The specific release areas are visible to the treating physician by inscriptions on the Vacuum Handpiece lid.

Component Descriptions

Anesthesia Needle Assembly

The sterile Cabochon System Needle Assembly includes a handle and 22G multi-hole needle which is guided in the tissue at the depth of the intended release utilizing the Vacuum Handpiece (and associated Guidance Platform). The handle (and needle) is placed on the Guidance Platform such that the guide pin on the underside of the handle fits in the entry point to the guidance track. The handle is gently moved to the end of the entry track at which point the needle tip pierces the skin captured within the Vacuum Handpiece. The handle is then moved into one of the four lateral Guidance Tracks and advanced until it stops, and the physician directed bolus of anesthesia is infiltrated. This step can then be repeated, without the needle being withdrawn completely, for the other lateral tracks assuring effective distribution of local anesthesia to the treatment site with a minimum of skin punctures.

Tissue Release Components

The Cabochon System is designed to provide tissue release with the added control of the depth through the use of the Vacuum Handpiece, and the Guidance Platform limits the size of the release area at that depth. The sterile Blade Assembly is attached to the Motor Module and the combined unit is then placed on the Guidance Platform such that the guide pin fits in the entry point to the guidance track. Prior to powering on the Motor Module, the Module is advanced through the skin insertion section of the guidance track and the blade tip pierces the skin, bringing the blade to the target depth. Once the Module is in the forward position on the insertion section of the track, the Motor Module is turned on, and the guidance track followed to create the release. The travel of the blade is controlled by the movement of the Blade Assembly and Motor Module through the guidance track. As with the anesthesia

handle, the guide pin (Figure 2) is designed so that the assembly is “locked” into the track. The treatment depths (adjustable by inverting the Vacuum Handpiece lid) provide a safe margin beneath the underside of the dermis and ensures the release is in the shallow fat layer where intended. The areas of release are visible on the lid, and the adequate capture of the tissue within the recess of the Vacuum Handpiece is visible to the user.

Non-sterile Reusable Components:

The Cabochon System electrical components include the Motor Module, Motor Controller and medical grade Power Supply, which are packaged together. The Motor Module connects to the Motor Controller which connects to the Power Supply. The mating of the Motor Module and the Controller can only occur in one orientation to ensure proper contact. The Reusable Components should be cleaned and disinfected prior to use per the cleaning and disinfection instruction provided in the labeling, but are not required to be sterilized.

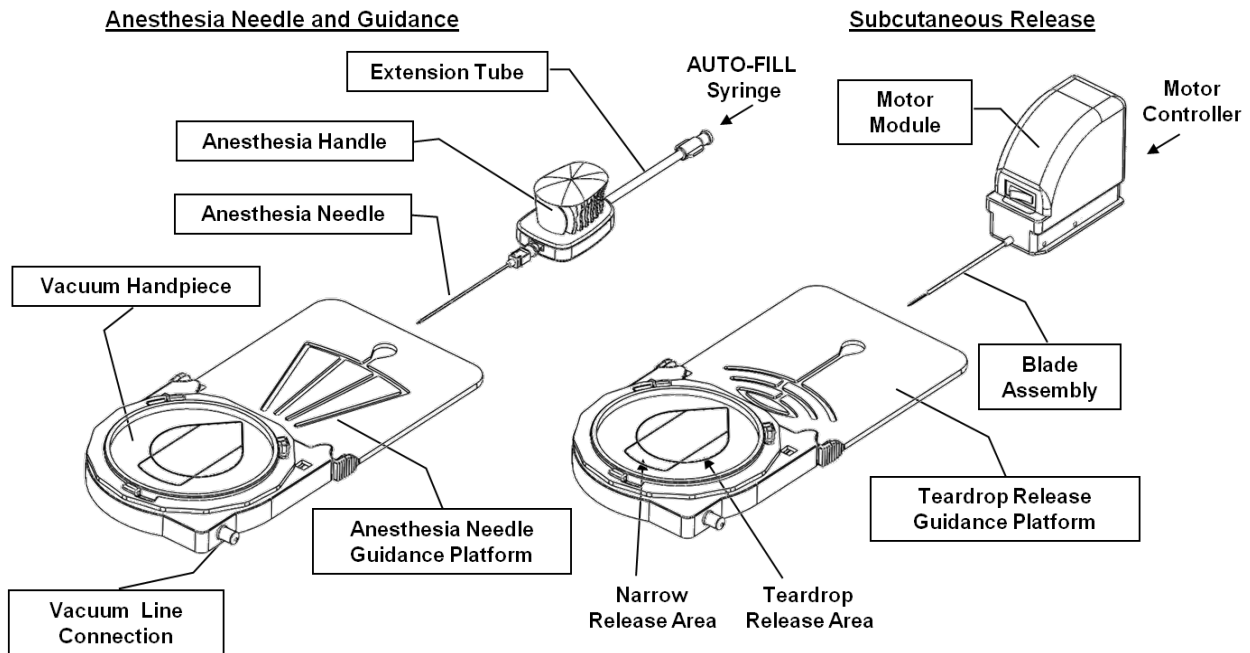


Figure 1. Components of the Cabochon System

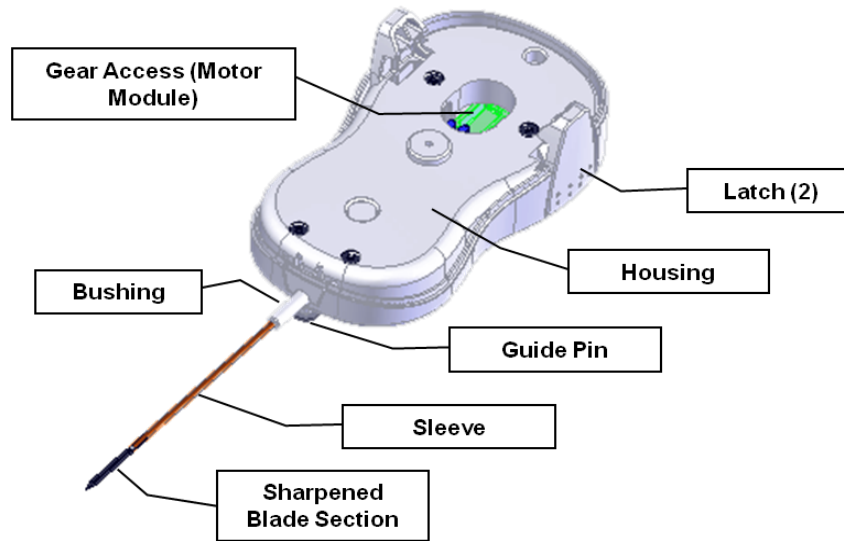


Figure 2. Release Blade Assembly

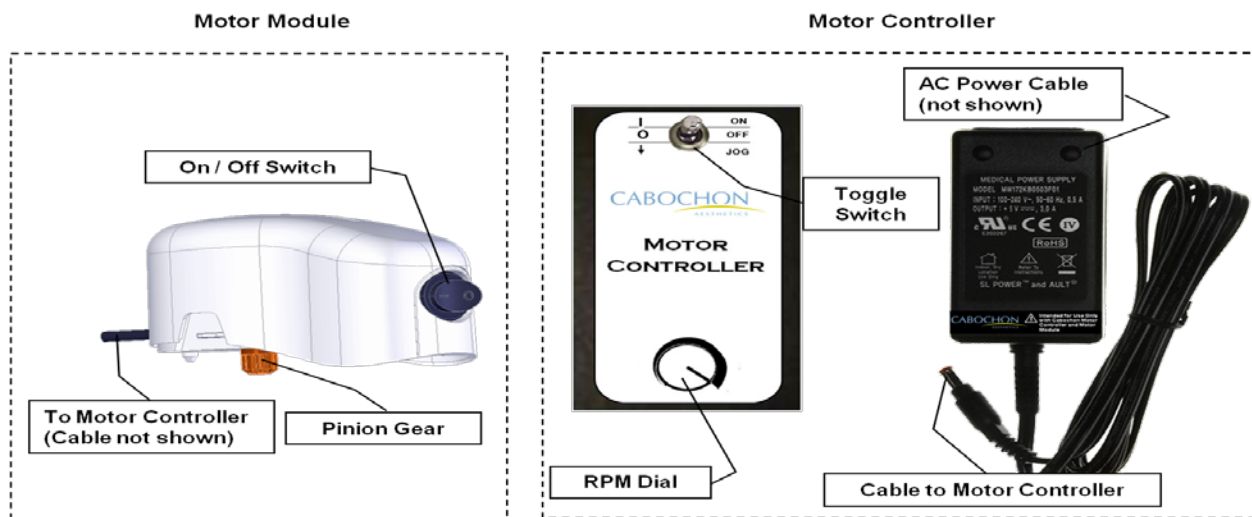


Figure 3. Cabochon System Reusable Components

SUMMARY OF PRECLINICAL STUDIES

BIOCOMPATIBILITY/MATERIALS

The materials which comprise the patient contact components of the Cabochon System are provided in Table 1 and have been evaluated with respect to their intended use per ISO 10993-1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. The biocompatibility data and required tests for the Cabochon System are listed in Table 1 and the Cabochon System conforms to the requirements of this safety standard.

Table 1. Patient Contact Materials

Product Component	Generic Material(s)	Biocompatibility Data	Required Tests per 10993-1
Nature of patient contact: External Communicating Device; Tissue Communicating; Limited Duration			
Blade Bushings/Tube	1. (b)(4) 2. (b)(4)	Manufacturers, certify ISO-10933-1 or USP Class VI Compliant. Data Maintained in Device Master Record.	1. Cytotoxicity 2. Sensitization 3. Intracutaneous reactivity 4. Systemic Toxicity (acute)
Blade	Stainless Steel	Recognized biomaterial per ASTM F899	N/A
Needle	Stainless Steel	Recognized biomaterial per ISO 9626	N/A
Nature of patient contact: Surface Device; Breached or Compromised Surfaces; Limited Duration			
Vacuum Handpiece Ring/Septum	1. (b)(4) 2. (b)(4)	Manufacturers, certify ISO-10933-1 or USP Class VI Compliant. Data Maintained in Device Master Record.	1. Cytotoxicity 2. Sensitization 3. Intracutaneous reactivity
Vacuum Handpiece Lid	(b)(4)		
Guidance Platforms	(b)(4)		

SHELF LIFE/STERILITY

The single use components of the Cabochon System are packaged as a Disposable Kit containing three assemblies: the Vacuum Handpiece Assembly (with Guidance platforms), Anesthesia Needle Assembly, and Released Blade Assembly. The Anesthesia and Blade Assemblies are each secured on a custom die card and the three assemblies are each sealed in a sterilization pouch which was selected with consideration of the sterilant penetration and maintenance of sterility. The set of three pouches is placed in an inner box and six Disposable Kits are configured in an outer shipper along with the User Manual. The Cabochon System Disposable Kit is sterilized by Ethylene Oxide (EO) gas (fixed chamber).

The sterilization process validation and routine monitoring comply with AAMI/ISO 11135:2007; Sterilization of Health Care Products – Ethylene Oxide – Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices. The validation was conducted using 4 production lots of product. The ethylene

oxide (EO) sterilization half cycle was used to demonstrate adequate destruction of biological indicators to demonstrate a greater than 12 log reduction for the full cycle and a sterility assurance level (SAL) of $\leq 10^{-6}$. Product was sampled for Product Sterility, Sterilant Gas Residuals and Limulus Amebocyte Lysate (LAL) testing. EO and ethylene chlorohydrins (ECH) residuals were measured to ensure they met the specified limits of ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.

The single use components of the Cabochon System are labeled for a shelf-life of 6 months. Verification of shelf life was based on AAMI/ISO 11135:1-2007; Sterilization of Health Care Products – Ethylene Oxide – Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices. The shelf life has been established through testing of multiple lots of product and packaging exposed to a combination of accelerated and real time aging. Accelerated aging was conducted on packaged product based on standard Arrhenius calculations. In addition, real time aging on the packaging was separately completed. All test devices and packages underwent environmental and transportation conditioning prior to testing (ASTM D4332 and D4169-09 cycle #13). Product was subjected to visual inspection as well as simulated use and mechanical integrity testing to verify performance. Packaging was subjected to visual inspection followed by bubble and peel testing (ASTM F2096-04 and F88-09). All performance was verified and the test results were deemed acceptable to verify a labeled shelf life of 6 months.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

Electrical safety testing was performed on the Cabochon System per the relevant requirements of IEC 60601-1:2003, Medical Electrical Equipment – Part 1: General Requirements for Safety. Testing for Electromagnetic Compatibility was performed per the relevant requirements of IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

The system is connected to MAINS through the use of a certified, medical external power supply, which in turn provides DC5V to the Motor Controller that then powers the hand-held Motor Module with its disposable Handpiece Assembly which includes the cutting blade. The system has been evaluated to not present a hazard under normal and single fault conditions, with regard to electrical shock (leakage current considerations), fire, energy and mechanical hazards, and generally uses certified components that are incorporated as intended and used within their ratings. EMC Testing was conducted to meet the requirements of Class B.

Based on successful completion of the testing, the Cabochon System is deemed compliant to relevant electrical and electromagnetic safety requirements of IEC 60601-1:2003 Medical Electrical Equipment – Part 1: General Requirements for Safety and testing as well as IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

MAGNETIC RESONANCE (MR) COMPATIBILITY

The Cabochon System is not intended to be used with or near Magnetic Resonance Imaging machines.

SOFTWARE

The Cabochon System does not incorporate software.

PERFORMANCE TESTING – NON-CLINICAL

As part of the design control and device development process, bench testing was successfully completed for the Cabochon System on multiple lots of aged and time-zero product. Testing was performed on finished, sterile devices that were exposed to environmental and transportation conditioning prior to testing (b)(4).

Testing included simulated use, durability and mechanical integrity. All devices were shown to meet pre-determined acceptance criteria.

As part of the design control and device development process, *ex vivo* studies were conducted in the (b)(4) to verify the performance of the Cabochon System. The *ex vivo* studies used sections of (b)(4) excised from the (b)(4). The tissue sections were harvested from (b)(4). Verification of the depth of tissue release and the release area was performed in this model.

A (b)(4) was also used to evaluate the tissue release. Verification of the depth of tissue release and the release area was performed in this model.

PERFORMANCE TESTING – IN VIVO EVALUATION

Animal:

As part of the design control and device development process, *in vivo* studies were conducted in the (b)(4) to verify the performance of the Cabochon System.

The *in vivo* studies were performed on (b)(4) under general anesthesia to verify the safety of the release methodology. Treatment with the Cabochon System was performed at different treatment time points prior to euthanasia to investigate the healing response. Findings included that bleeding was minor at all the treatment sites, the plane and areas of tissue release were within specification and the area of release was as expected. There were no necrotic areas noted in the dermis at any time point, as determined by gross and histological evaluation.

Clinical:

Feasibility clinical testing of the Cabochon System was conducted to refine instructions for safe and effective use including patient selection and surgical technique in 1 outside the US (OUS) and 1 US center where 56 subjects received treatment with the device with follow-up out to 1-year in the US site. There were no serious or unanticipated adverse events related to the device or procedure, and the effectiveness endpoints were achieved. Data from the feasibility study was also used to develop an appropriate pivotal study.

The *in vivo* performance of the Cabochon System was also evaluated in a pivotal clinical study conducted under IDE (b)(4) . A prospective, multi-center, non-randomized open label study for the treatment of cellulite of the buttock and thigh areas in 55 subjects was conducted in 3 US centers. All subjects served as their own control and underwent a single treatment with the Cabochon System. All subjects underwent follow-up assessments at 3 days, 14 days, 1 month, and 3 months post-treatment. The subject inclusion/exclusion criteria limited inclusion to female subjects between the ages of 18 and 55 with moderate to severe cellulite and a body mass index (BMI) less than 35. The enrolled study population included female subjects between the ages of 25 and 55 with moderate to severe cellulite and BMI between 18 and 35. The subjects were asked to rate their satisfaction with their appearance and pain. Photographs were taken in accordance with a protocol-specific procedure at baseline and each follow-up. An independent and blinded review of the photographs before treatment and at 3 months post-treatment was used to verify the effectiveness of the procedure. A data safety monitoring board (DSMB) was formed and independently reviewed adverse event information to provide safety oversight for the study.

The study population included female subjects between the ages of 25 and 55 with moderate to severe cellulite and BMI between 18 and 35. In addition, subjects were excluded that smoked or had recently quit smoking (within the last 6 months).

No Unanticipated Adverse Device Effects (UADE) and no Serious Adverse Events (SAE) occurred in the study. Therefore, as no SAE were determined to be related to the Cabochon system or procedure, the primary safety endpoint for the study was achieved. There were two minor, resolved adverse events (AE) in total determined to be related to the treatment or procedure: 1) a superficial wound created from scratching at a treatment site, and 2) itching on the inner thighs from wearing a compression garment.

Bruising and soreness were reported early by most subjects, with no reports after 1 month. Expected treatment effects at 3 months were minor and consistent with the mechanism of action: palpable very small areas of firmness (or softness) visible in only one subject and minor, infrequent sensations of “tingling” in two subjects.

In the clinical study, effectiveness was evaluated by both subject satisfaction and improvement assessment by independent physician evaluation of subject photographs taken before and 3 months after treatment. This evaluation was conducted by an independent firm in accordance with the study protocol whereby the evaluators were disclosed nothing about the sponsor, the investigational device or the clinical investigators. A total of three independent physician evaluators were selected, individually trained, and monitored throughout the evaluation. In the evaluation, blinded before (baseline) and after photographs were provided side by side in randomized orientation (L-R) and the physician evaluators were asked to identify the baseline and after photographs, rate the overall improvement according to a Global Aesthetic Improvement Scale (GAIS), and then (b) (4)

All reliability and repeatability measures were met and validated the methodology.

The overall study success criterion was achievement of a safe and clinically significant improvement in the appearance of cellulite in the treated subjects as defined by the powered endpoints:

- The primary endpoint was met: achievement of (b) (4) point average reduction in the (b) (4) as determined by independent physician assessment of subject photographs taken before and 3 months after treatment.
 - The average improvement (Baseline-three months) was (b) (4) with the one-sided lower (b) (4) confidence limit of a (b) (4) point improvement (Baseline-three months).
- The powered secondary endpoint was met: improvement of one grade or more in severity (none, mild, moderate, severe) in (b) (4) of treated subjects as determined by independent physician assessment of subject photographs taken before and 3 months after treatment.
 - (b) (4) of treated subjects had improvement of 1 grade with a lower two-sided (b) (4) confidence limit of (b) (4)

All additional secondary measures were also achieved or acceptable:

- The secondary effectiveness measure of (b) (4) or higher average rate of correct selection by independent physician assessment of blinded subject photographs taken before and 3 months after treatment was achieved.
 - The average rate of correct selection was (b) (4) with a lower two-sided (b) (4) confidence limit of (b) (4)
- The secondary effectiveness measure of improvement in subject appearance according to a Global Aesthetic Improvement Scale (GAIS) evaluated by independent physician assessment of subject photographs taken before and 3 months after treatment was achieved.
 - (b) (4) of the subjects had noticeable improvement by the GAIS and (b) (4) were characterized as having marked improvement or better.
- The secondary measure of subject satisfaction with the appearance of their cellulite as evaluated by a (b) (4) scale at the 3 month follow-up was achieved.
 - Over (b) (4) of the subjects were either satisfied or very satisfied.
- The additional study measure of subject reported pain was acceptable. Using a (b) (4) numerical rating scale (NRS), subjects were asked to rate and then describe any pain in the treatment area at baseline, immediately post-procedure and at each of the follow-ups. The highest procedural pain levels were recorded during anesthetic delivery and were consistent with similar cosmetic procedures.
 - On average, (b) (4) of subjects rated pain (b) (4) at 3 days, and over (b) (4) rated pain (b) (4) thereafter. The majority of the experienced pain was described as “aching” and occurred only with touch or pressure.

In conclusion, all the study endpoints were achieved. The *in vivo* performance data collected in the pivotal study demonstrates that the Cabochon System is both safe and effective for the short-term improvement in the appearance of cellulite in the buttock and thigh locations.

LABELING

The Cabochon System complies with the labeling requirements under 21 CFR § 801 and is labeled for prescription use only. The device labeling includes a summary of the clinical trial data provided to the FDA.

RISKS TO HEALTH

The risks that may be associated with the use of a powered surgical instrument for improvement in the appearance of cellulite are identified in Table 2. The measures necessary to mitigate these identified risks are also identified in Table 2.

Table 2. Identified Risks and Mitigation Measures for a Powered Surgical Instrument for improvement in the appearance of cellulite

Identified Risk	Mitigation Measures
Mechanical Injury (excessive treatment or treatment of non-intended areas)	Non-clinical Testing In Vivo Evaluation
Infection	Sterility Assurance Testing Shelf-life Testing
Electrical Shock	Electrical Safety Testing
Electromagnetic Interference	Electromagnetic Compatibility (EMC) Testing
Adverse Tissue Reaction	Biocompatibility Testing
Use Error	In Vivo Evaluation Labeling

SPECIAL CONTROLS

In addition to the general controls of the FD&C Act, the Cabochon System is subject to the following special controls:

1. Non-clinical testing must be performed to demonstrate that the device meets all design specifications and performance requirements, and to demonstrate durability and mechanical integrity of the device.
2. *In vivo* evaluation of the device must demonstrate device performance, including the safety of the release methodology and blood loss at the treatment sites.
3. All elements of the device that may contact the patient must be demonstrated to be biocompatible.
4. Electrical safety and electromagnetic compatibility of the device must be demonstrated.
5. The labeling must include a summary of *in vivo* evaluation data and all the device specific warnings, precautions, and/or contraindications.

6. Sterility and shelf life testing for the device must demonstrate the sterility of patient contacting components and the shelf-life of these components.

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

BENEFIT/RISK DETERMINATION

Risks

The risks of the device are based on the non-clinical and *in vivo* testing conducted for the Cabochon System as well as the risk analysis provided with the 510(k) submission (K101231), which has been conducted under the Design Controls requirements of the Quality System regulations (21 CFR 820) using FDA-recognized standard, ISO 14971:2007, Medical devices - Application of risk management to medical devices. The identified risks and mitigation measures for the Cabochon System are summarized in Table 2 above and this analysis documents the absence of unreasonable risk of illness or injury associated with the use of the device.

Benefits

The probable benefits of the Cabochon System are based on *in vivo* data collected in a clinical study as described above. The Cabochon System has been studied in a pivotal study and has been shown to produce demonstrable improvement in the appearance of cellulite as evaluated by both independent physicians and the subjects themselves. The number of subjects that were satisfied with their appearance improved from 0% at baseline to over 85% with the Cabochon treatment. An independent and blinded review of the before and after treatment photographs was conducted by three independent physician evaluators who were asked to quantify the severity of cellulite both before and after treatment according to a validated 0-5 point Cellulite Severity Scale. Cellulite Severity Scale was improved (decreased) by an average of 2.1 points overall ($p < 0.0001$) and 93% of all subjects were scored to have improved by at least 1 full Severity Grade (none, mild, moderate, severe). The magnitude of the treatment effect was large compared to the success criteria for all endpoints. There is a very high probability that a patient for whom the device is intended will experience the demonstrated benefit.

Therefore, there is reasonable assurance that the Cabochon System is effective based on valid scientific evidence that, in a significant portion of the target population, the use of this device for its intended uses and conditions of use, provides improvement in the appearance of cellulite that meets the needs of physicians and patients.

In conclusion, based on the available information summarized above, the *in vivo* data supports that for the short-term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females, the probable benefits outweigh the probable risks for the Cabochon System. The device provides substantial benefits; and the risks can be appropriately mitigated by the use of general and the identified special controls.

CONCLUSION

The de novo for the Cabochon System is granted and the device is classified under the following:

Product Code: OUP

Device Type: Powered surgical instrument for improvement in the appearance of cellulite

Class: II

Regulation: 21 CFR 878.4790