DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 12, 2013

Ben Brian, Ph.D.
Chief Executive Officer
Cabochon Aesthetics, Inc.
127 Independence Drive
Menlo Park, California 94025

Re: K101231
Device Name: Cabochon System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 878.4790
Regulation Name: Powered surgical instrument for improvement in the appearance of cellulite
Regulatory Classification: Class II
Product Code: OUP
Dated: October 29, 2011
Received: October 31, 2011

Dear Dr. Brian:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Cabochon System, a prescription device under 21 CFR Part 801.109 that is indicated for the short term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Cabochon System, and substantially equivalent devices of this generic type, into class II under the generic name, Powered surgical instrument for improvement in the appearance of cellulite.

FDA identifies this generic type of device as:

> **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.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally

referred to as post-amendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on March 14, 2011 automatically classifying the Cabochon System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On October 31, 2011, FDA received your *de novo* requesting classification of the Cabochon System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Cabochon System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the Cabochon System indicated for the short term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures with the device type are summarized in Table 1.

Table 1 - Identified Risks to Health and Mitigation Measures

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

In addition to the general controls of the FD&C Act, the Powered surgical instrument for improvement in the appearance of cellulite 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. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the

premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the powered surgical instrument for improvement in the appearance of cellulite they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Mr. Mark N. Melkerson at 301-796-5650.

Sincerely yours,

Jonette R. Foy -S

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