DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 12, 2016

Syneron Candela Corporation
% Janice Hogan
Regulatory Counsel
Hogan Lovells Us Llp
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Philadelphia, Pennsylvania 19103

Re: K161043
Trade/Device Name: Profound System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX, GEI
Dated: August 15, 2016
Received: August 15, 2016

Dear Janice Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page*

510(k) Number *(if known)*

K161043

Device Name

Profound System

Indications for Use *(Describe)*

The Profound System is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. Specifically, the 25º Dermal handpiece and cartridge are used for percutaneous treatment of facial wrinkles, and the 75º SubQ handpiece and cartridge are used to improve the appearance of cellulite in patients with Fitzpatrick skin types I-III as supported by long-term clinical data (6 months).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**510(k) Summary**
**Profound System**


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**Date prepared:** September 12, 2016

**Trade Name:** Profound System

**Common Name:** Electrosurgical unit and accessories

**Classification:** Class II per 21 C.F.R. § 878.4400 – Electrosurgical cutting and coagulation device and accessories
Product Code PBX, GEI

**Predicate Devices:**

Primary Predicate Devices
Syneron-Candela's Profound System (K082391, K080145)
Viora Ltd.'s V10 System (K150035)

Reference Predicate Device
Cynosure's Cellulaze Laser (K123407)

**Intended Use / Indications for Use:**

The Profound System is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. Specifically, the 25º Dermal handpiece and cartridge are used for percutaneous treatment of facial wrinkles, and the 75º SubQ handpiece and cartridge are used to improve the appearance of cellulite in patients with Fitzpatrick skin types I-III as supported by long-term clinical data (6 months).

**Device Description:**

The Profound System is comprised of the following components: a re-usable console containing a

radiofrequency (RF) generator and graphical user interface; two re-usable treatment applicators; and two disposable, single use, sterile electrode cartridges. Bipolar RF energy is delivered from the RF generator through the electrodes into the dermal layers beneath the surface of the skin. The volume of the treated area is defined by the geometry of the individual micro-electrode needle pairs, which are all electrically isolated from each other and controlled independently by separated RF channels within the console. In addition, temperature sensors provide real-time feedback of tissue temperature. The treatment dose is controlled by the physician.

**Technological Characteristics:**

The Profound System has similar technological characteristics as its predicates. The primary purpose of this submission is to expand the Profound's indications for use to include long-term improvement in the appearance of cellulite.

The Profound design and components are very similar to those previously cleared. Specifically, the cleared 25º Dermal handpiece and associated electrode cartridge have remained essentially the same, with minor hardware and software changes. The company has also added an option for the physician to use a 75º SubQ handpiece and associated electrode cartridge. The modified device is based on the same principles of operation, *i.e.,* thermal heating. The RF frequency and maximum output voltage per channel are the same as for the cleared Profound System. Same as the previously cleared Profound, the system has an electrically powered console with a graphical user interface through which the physician pre-sets treatment parameters (as appropriate for each patient) and obtains real-time feedback regarding ongoing treatment. Minor software changes have been made and the updated software has been subjected to verification and validation. The technological differences compared to the predicates do not raise any different types of safety or effectiveness questions, because the modified device operates in the same manner and the treatment parameters are the same as or within the range of the predicates.

**Summary of Substantial Equivalence:**

The subject Profound System has the same intended use and similar indications for use as its predicates. The indications of the subject device are the same as those of the predicate, K082391, except for the proposed additional indication for use: "…improve the appearance of cellulite in patients with Fitzpatrick skin types I-III as supported by long-term clinical data (6 months)." The newly added indications for use, while not the same, is similar to the Viora V10 System predicate which is cleared for "…Temporary reduction in the appearance of cellulite." Moreover, the newly added indications for use is similar to the reference predicate device, Cellulaze (K123407), indications for use, which is as follows: "Cynosure Cellulaze™ laser is intended for the improvement in the appearance of cellulite as supported by long-term clinical data (at least 6 months with no observed reduction in treatment benefits up to 9 months of observation)."

The subject device and the primary predicate devices are radio frequency (RF) based electrosurgical devices. The subject device has similar components and the same energy output as the Profound primary predicate, and minor design changes to the previously cleared console and 25º handpiece do not impact device performance. The added 75º cartridge and associated handpiece have similar technological characteristics as the previously cleared cartridge and handpiece.

The similarities and differences in terms of indications for use and technological characteristics between the subject and predicate devices are summarized in the below side by side comparison table. To address the differences in the indications for use and technological parameters, a clinical study was performed, as described below in the Performance Data section of this 510(k) Summary.

The clinical data support substantial equivalence of the Profound compared to its predicate devices. The technological differences have also been evaluated in bench testing. Minor software changes to accommodate the expanded technological features have been verified and validated.

| Product | Syneron-Candela Corp.'s Profound System (K161043) | Primaeva Medical, Inc.'s Miratone System (K082391, K080145) | Viora Ltd.'s V10 System (K150035) |
|---|---|---|---|
| **Intended Use/ Indications for Use** | The Profound System is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. Specifically, the 25º Dermal handpiece and cartridge are used for percutaneous treatment of facial wrinkles, and the 75º SubQ handpiece and cartridge are used to improve the appearance of cellulite in patients with Fitzpatrick skin types I-III as supported by long-term clinical data (6 months). | The Primaeva Medical Miratone System is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles. | The Viora V10 system is intended for dermatological procedures. The V-Form Handpiece, with Body-Contour (BC) and Facial-Contour (FC) applicators, is indicated for delivering non-thermal RF combined with massage:<br>• relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation and<br>• Temporary reduction in the appearance of cellulite. |
| **Product Code** | PBX, GEI | GEI | PBX, ISA |
| **Energy Type** | Bipolar fractionated RF | Bipolar fractionated RF | Bipolar RF, Vacuum |
| **RF Frequency** | 460 +/- 5kHz | 460 +/- 5kHz | 0.8, 1.7, or 2.45 MHz, or combination of all 3 frequencies |
| **Components** | • RF generator with user interface<br>• Reusable electrode insertion device/applicators (25º with cooling plate and 75º)<br>• Single patient use, disposable, 25º and 75º electrode cartridges | • RF generator with user interface<br>• Cooler controller and handpiece/applicator<br>• Reusable electrode insertion device/applicator<br>• Single patient use disposable, 25º electrode cartridge. | • Console (RF generator, user interface, etc.)<br>• Applicators (with cable, connector to console, and vacuum pump; 2 available for cellulite indication) |
| **Maximum Output Voltage** | 84 VRMS | 84 VRMS | Not specified |
| **Channels** | 25º applicator: 5 independent channels (electrode pairs)<br>75º applicator: 7 independent channels | 25º applicator: 5 independent channels (electrode pairs) | Multi-channel;<br>6 electrodes (V-Form handpiece) |
| **Target Temperature Range** | 65-75ºC +/- 1ºC increments | 65-75ºC +/- 1ºC increments | Not specified |
| **Treatment Area Width** | 14 mm for the 25º mode (5 pairs)<br>20 mm for the 75º mode (7 pairs) | 14 mm (5 pairs) | BC applicator: 97 x 83 mm<br>FC applicator: 0-24 mm |
| **User Interface** | GUI – color LCD display | GUI – color LCD display | Display unit |
| **System Dimensions** | 125 x 46.5 x 44.5 cm / 29.5 x 18.5 x 17.5 inches | 125 x 46.5 x 44.5 cm / 29.5 x 18.5 x 17.5 inches | 45 x 35 x 40 cm |

| Product | Syneron-Candela Corp.'s Profound System (K161043) | Primaeva Medical, Inc.'s Miratone System (K082391, K080145) | Viora Ltd.'s V10 System (K150035) |
|---|---|---|---|
| **Electrical Requirements** | 100-240 VAC; 2.5 A; 50-60 Hz; single phase | 100-240 VAC; 2.5 A; 50-60 Hz; single phase | 90-264 VAC; 50-60 Hz; single phase |
| **Sterilization** | Cartridges are sterilized | Cartridges are sterilized | Not specified |

In summary, minor differences between the subject Profound and the predicates do not present different types of safety or effectiveness questions, since the Profound's energy parameters are similar to or within the range of the predicates and the device operates in the same manner and for the same general intended use as the primary predicates. Further, the device's safety and performance have been confirmed by results of both clinical and non-clinical investigations. Therefore, the subject Profound System has the same intended use and similar indications for use, technological characteristics, and principles of operation as the predicate devices.

**Performance Data:**

Electrical Safety and Electromagnetic Compatibility: Electrical safety and electromagnetic compatibility (EMC) testing for the modified Profound System was conducted by an independent test laboratory in accordance with the applicable standards (IEC 60601-1, *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*, EN 60601-1-2, *Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests*, and IEC 60601-2-2, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*). The Profound System was determined to be in conformance with these standards.

Biocompatibility: The biocompatibility of the Profound device has been established per ISO 10993 guidelines as well as comparison to previously cleared Syneron applicators using the same chrome plating for the same type and duration of patient contact.

Software: Software verification and validation testing was conducted and results were found acceptable for software release.

Bench Testing: Performance testing on the RF generator, 25º Dermal handpiece, and 25º Dermal cartridge was previously conducted and confirmed device performance. Bench testing performed on the new 75º SubQ handpiece and cartridge demonstrated that the modified device performs as intended and device outputs met specifications.

Clinical Data: In support of this 510(k), a single arm, self-controlled, multi-center study was conducted to evaluate the safety and effectiveness of the Profound for improving cellulite appearance. The clinical study evaluated 50 treated subjects (100 thighs), all females, across all skin types. Mean age was 44 years and the majority of the subjects were Caucasian. Data demonstrated that the Profound performs as intended when used for this indication. Treatment with the Profound did not lead to any device-related serious adverse events. The mean pain level reported (3.74/10) reflects patient comfort when the procedure is performed as indicated, *i.e.*, with tumescent anesthesia and cold air. Anticipated treatment responses reported immediately after the procedure (*e.g.,* erythema, edema) all completely resolved without medical intervention. The study met the primary endpoint, where 94% of treated thighs demonstrated improvement in cellulite

appearance as assessed by blinded review at 3 months following treatment when considering improvement in dimples and/or undulation irregularities. When considering improvement in each cellulite feature separately, 86% of the treated thighs (of the 80 thighs with dimples at baseline) showed improvement in dimples, and 76% of the thighs (all thighs had undulation at baseline) showed improvement in undulation irregularities. Per subject results were similar, where 88% (37/42) of the treated subjects showed improvement in both thighs in dimples and/or undulation at 3 months follow up. When considering each cellulite feature separately, 71% of the treated subjects showed improvement in dimples in both thighs, and 64% showed improvement in undulation irregularities in both thighs.

Further, additional assessments of treatment effectiveness were also favorable. These included blinded review at 6 months post-treatment, where improvement in cellulite appearance was maintained at 6 months follow up; 93% (78/84) of the treated thighs (per-subject success (both thighs) of 86%) showed improvement in cellulite appearance at 6 months post-treatment compared to baseline based on blinded review. In addition, assessments also included non-blinded, open-label assessments by investigators and patients of the severity of cellulitic features, overall improvement in cellulite appearance, and satisfaction with treatment at 1, 3, and 6 months following treatment. Therefore, the study results for the subject device did not present any different types of safety or effectiveness questions as compared to the predicates. The study design and results are summarized in the table below.

| | |
|---|---|
| Study Design | Prospective, single-arm, self-controlled, multicenter clinical study |
| Sample size | 50 patients (100 thighs) were treated across 4 U.S. sites. |
| Principal Eligibility Criteria | • Seeking treatment of cellulite in the upper thighs areas<br>• Presenting with cellulite stage II or III as graded using the Nurnberger-Muller scale classification<br>• Healthy females ages 25 to 60 years of age<br>• Willing to receive the proposed Profound treatment and comply with the follow-up protocol |
| Follow up intervals | 4 follow-up visits: 1 week, 1 month, 3 months and 6 months following treatment. |
| Endpoints | **Primary**: The study primary endpoint was achieved when 80% of thighs showed at least 1 point level of improvement in the appearance of cellulite at 3 month follow-up visit relative to baseline photos based on blinded review.<br><br>**Secondary**:<br>- Cellulite appearance improvement by blinded evaluators at 6 months post treatment visit.<br>- Cellulite appearance improvement by study investigators.<br>- Investigator improvement and satisfaction assessments.<br>- Subject improvement and satisfaction assessments. |

| | |
|---|---|
| Effectiveness Results | **Primary**: Met endpoint; 94% (79/84) of the treated thighs based on observed data had an improvement in cellulite appearance per blinded review. 88% (37/42) of the treated subjects showed improvement in both thighs in dimples and/or undulation at 3 months follow up.<br><br>**Secondary**:<br>- Improvement in cellulite appearance was maintained at 6 months follow up; 93% (78/84) of the treated thighs (per-subject success (both thighs) of 86%) showed improvement in cellulite appearance at 6 months post-treatment compared to baseline based on blinded review.<br>- Investigator cellulite reduction assessment results demonstrated progressively improved treatment effects for the large majority of thighs at 3 and 6 months following treatment.<br>- Cellulite improvement per the Nurnberger-Muller scale also demonstrated increasing levels of improvement throughout the study (majority of the thighs showed improvement at 3 and 6 months following treatment).<br>- Nearly all of the thighs showed improvement at 1 month following treatment and all thighs showed improvement at both 3 and 6 months following treatment.<br>- Investigator satisfaction increased gradually along the study course and was demonstrated for the majority of the subjects at 3 and 6 month follow up.<br>- Subject improvement results showed moderate to excellent reduction for most of the thighs at 3 and 6 month follow up.<br>- Subject satisfaction was reported by a majority of subjects at 3 and 6 month follow-up visits. |
| Safety Results | Of the 50 total subjects, only 3 subjects reported a total of 3 adverse events. None were serious and each event resolved during the study. Anticipated treatment-associated responses experienced during the first week following treatment were also reported. None of the immediate responses were observed at the next visit (i.e., 1 month follow-up visit). |

The distribution of numbers of insertions in the study suggested that most treatments were covered by a range of up to 300 insertions per thigh, or up to a maximum treatment density of 1.333. No clear dose-response relationship was observed, and treatment beyond these levels has not been shown to improve outcomes and is not recommended.

**Conclusions:**

Testing of the Profound System demonstrated that the device performs as intended with a favorable safety profile. The non-clinical data further support device safety. Verification and validation testing of the modified software demonstrates that the device performs as intended. Thus, the Profound System is substantially equivalent to the predicate devices.