December 16, 2021

Candela Corporation
Rina Ordonez
251 Locke Dr
Marlborough, Massachusetts 01752

Re: K211217
Trade/Device Name: Profound Matrix
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 19, 2021
Received: November 22, 2021

Dear Rina Ordonez:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211217

Device Name
Profound Matrix

Indications for Use *(Describe)*
The PROFOUND MATRIX SYSTEM is intended for dermatological procedures, as follows:

The MATRIX PRO applicator is indicated for general dermatological procedures for electrocoagulation and hemostasis.

The SUBLATIVE RF applicator is indicated for dermatological procedures requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles. At higher energy levels greater than 62mJ/pin, the Sublative RF applicator is limited to Fitzpatrick Skin Types I-IV.

The SUBLIME applicator is indicated for non-invasive wrinkle treatment. At higher energy levels, greater than 100 J/ cm3, the Sublime applicator is limited to Fitzpatrick Skin Types I-IV.

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 – K211217
Profound Matrix System

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

1. DATE PREPARED

April 21, 2021

2. SUBMITTER

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3. OFFICIAL CORRESPONDENT

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4. DEVICE INFORMATION

Proprietary Name:	Profound Matrix™
Common/Usual Name:	Electrosurgical coagulation device and accessory
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR Part 878.4400)
Product Code:	GEI
Device Classification:	Class II

5. PREDICATE DEVICE

Primary Predicate: Lutronic Infini (K121481)
Reference Devices: Syneron Medical Ltd eTwo Skin Treatment System (K141507, K110672), Syneron Candela Corporation Profound System (K161043)

6. INTENDED USE/INDICATION FOR USE

The PROFOUND MATRIX SYSTEM is intended for dermatological procedures, as follows:

The MATRIX PRO applicator is indicated for general dermatological procedures for electrocoagulation and hemostasis.

The SUBLATIVE RF applicator is indicated for dermatological procedures requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles. At higher energy levels greater than 62 mJ/pin, the Sublative RF applicator is limited toFitzpatrick Skin Types I-IV.

The SUBLIME applicator is indicated for non-invasive wrinkles treatment. At higher energy levels greater than 100 J/cm^3, the Sublime applicator is limited to Fitzpatrick Skin Types I-IV.

7. DEVICE DESCRIPTION

The Profound Matrix System combines three existing technologies and applications for dermatological procedures. Each respective technology is used in one of the three applicators designed for the Profound Matrix System. These three applicators are named: Matrix Pro, Sublative RF and Sublime.

The Matrix Pro applicator is designed to deliver bipolar, non-ablative radiofrequency energy through a 7x7 matrix/grid of sterile microneedles to the skin in a fractional manner. The microneedles can be set up to pulse a maximum of three depths during each insertion of the matrix/grid of microneedles with a maximum depth of up to 3.5mm.

The Sublative RF applicator delivers bipolar radiofrequency (RF) to the skin surface viaan array of multi-electrode pin tips. The applicator delivers bipolar RF energy to the skin, which results in heating of demarcated spots to temperatures that ablate and resurface at contact points of the multi-electrode pins.

The Sublime applicator uses a combination of an infrared (IR) light source and bipolar radiofrequency (RF) to bulk heat the dermis and affect dermal collagen in order to treat wrinkles. The bulk heating of the dermal layers refers to the gradual and gentle accumulation of heat with each additional pass performed.

8. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics comparison between the Profound Matrix System and its predicates is done per applicator and system console, as each applicator incorporates different technology, and the console enables each technology.

The following table (Table 8-1) compares the key technological characteristics and features of the Profound Matrix System to the predicate device. The tables that follow compare the key technical characteristics and features of the different applicators with predicate and reference devices (Tables 8-2, 8-3, and 8-4).

Table 8-1: SYSTEM LEVEL - Technical Comparison of Subject System Device with Predicate and Reference Devices

Specifications	**Subject Device** Profound Matrix	**Predicate Device** Infini Radiofrequency System (K121481)	**Reference Device** eTwo (K141507)	**Reference Device** Profound System (K161043)
Indications for Use	The PROFOUND MATRIX SYSTEM is Intended for dermatological procedures, as follows: The MATRIX PRO applicator is intended for use in dermatologic, procedures for electrocoagulation and hemostasis. The SUBLATIVE RF applicator is indicated for dermatological procedures requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles. At higher energy levels greater than 62 mJ/pin, the Sublative RF applicator is limited to Fitzpatrick skin types I-IV. The SUBLIME applicator is indicated for non-invasive wrinkles treatment. At	The INFINI Radiofrequency System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles.	The eTwo Skin Treatment System is intended for dermatological procedures. The Sublative RF applicator is indicated for dermatological procedures requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles. At higher energy levels greater than 62 mJ/pin, the Sublative RF applicator is limited to skin types I-IV. The Sublime applicator is indicated for non-invasive wrinkles treatment. At higher energy levels greater than 100 J/cm3, the Sublime applicator is	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).

Specifications	**Subject Device** Profound Matrix	**Predicate Device** Infini Radiofrequency System (K121481)	**Reference Device** eTwo (K141507)	**Reference Device** Profound System (K161043)
	higher energy levels greater than 100 J/cm3, the Sublime applicator is limited to Fitzpatrick skin types I-IV		limited to skin types I-IV.	
Device Dimensions	39.4 x 57.4 x 135.6 cm	36.2 x 40.9 x 171.3 cm	30 x 23 x 53 cm	46.5x 44.5 x 125 cm
Weight (Pounds, Kg)	50, 22.5	61.7, 28	18.7, 8.5	55, 23
Power Supply	Yes	Yes	Yes	Yes
ElectricalRating	Single phase 100-240V, 3A,50/60Hz	Single phase AC220-230V, 50-60Hz Power consumption: 500VA (Fuse: 250V/6.3A)	Single phase 100-240 VAC, 3A, 50-60Hz	Single phase 100-240 V, 2.5A,50-60Hz
User Interface	Graphics with touchscreen	Graphics with touchscreen	Graphics with touchscreen	Graphics with touchscreen
Applicators	Matrix Pro (RF microneedles) Sublative Sublime	RF microneedles	Sublative Sublime	Dermal RF Subcutaneous RF
Treatment Modes	Matrix Pro – Manual Sublative – Manual Sublime – Manual	Manual and Auto	Sublative – Manual Sublime – Manual	Dermal – Manual Subcutaneous – Manual
RF Energy Activation	Fingerswitch or Footswitch	Fingerswitch or Footswitch	Fingerswitch	Fingerswitch
Treatment Settings	Matrix Pro – needle depth and RF energy Sublative – RF energy per pin Sublime – RF power density and IR fluence	Manual mode – needle depth, RF level (power), and RF pulse duration. Auto mode – Location (Lower face Submental, Neck, Forehead, Periorbital), Pass (1 to 3), Intensity (Low, Medium, High)	Sublative – RF energy per pin Sublime – RF power density and IR fluence	Dermal, Subcutaneous – Treatment temperature and treatment time

Table 8-2: HANDPIECE AND CARTRIDGE LEVEL - Technical Comparison of Subject Device with Predicate and Reference Devices

Specifications	Profound Matrix-Matrix Pro (Subject Device)	Infini Infini Handpiece K121481 (Predicate Device)	Profound Profound Dermal K161043 (Reference Device #2)
Applicator Type	Short Pulse Microneedling	Short Pulse Microneedling	Long Pulse Microneedling
Applicator Dimensions	14.4 x 14.3 cm / 5.7 x 5.6" [W x H]	Unknown	19.4 x 13.9 cm / 7.6 x 5.5"
Energy Source	Matrix Pro: Radio Frequency	Infini handpiece: Radio Frequency	Profound Dermal Cartridge: Radio Frequency
RF Mode of operation	Bipolar	Bipolar	Bipolar
RF Frequency	1 MHz	1 MHz	460±5 kHz
Disposable Tip Area Coverage & Injection Pattern	1 cm^2 Square	49 needle Tip 1 cm^2 16 needle Tip 0.36 cm^2 Square	1.4 cm x 0.16 cm Pseudo-Linear
RF Pulse duration	Up to 280 ms	10 to 1000 ms	3-5 seconds
# Of needles	49 (7 x 7)	49 (7 x 7) or 16 (4 x 4)	10 (5 pairs of 2)
# Of treatment levels per insertion	1, 2 or 3	1	1
# Of treatment zones per insertion	49, 98, or 147	49	5
Maximum RF power	50 W	50 W	15 W
Energy delivered per treatment level	1 – 4 J	25 mJ – 50 J 1 – 20 Levels*	Unknown
Energy delivered per treatment zone	20 – 82 mJ	0.51 mJ – 1.02 J	Unknown
Controlled energy delivered	Yes, Controlled by sampling impedance	No Not controlled	No Not controlled
Controlled thermal dose	No	No	Yes, PID temperature control 50-75°C ±10°C with treatment duration of 3-5 seconds
Repetition Rate**	No existing setting	No existing setting	No existing setting
Needle uncoated	0.6 mm	0.3 mm	3 mm

Specifications	Profound Matrix-Matrix Pro (Subject Device)	Infini Infini Handpiece K121481 (Predicate Device)	Profound Profound Dermal K161043 (Reference Device #2)
length			
Needle insertion angle to tissue	90°	90°	25°
Insertion depth range	0.8 - 3.5 mm Steps of 0.8 mm	0.5 - 3.5 mm Recommended steps of at least 0.5 mm	2 mm
Accuracy of insertion depth	±0.4 mm	Unknown	Unknown
Needle Thickness / Diameter	34 gauge 160 µm	32 gauge 200 µm	32 gauge 200 µm
Treatment Duration	Up to 4.5 sec	10-400 ms (10 ms steps) 400-1000 ms (50 ms steps)	5 sec ±0.2 sec increments
Rated Voltage	275 Vrms	Unknown	84 Vrms
Mode of Operation	Microneedles are inserted into the dermis where they emit bipolar RF energy from their electrode needle tips, thermally damaging surrounding tissue and stimulating a tissue healing process.	Microneedles are inserted into the dermis where they emit bipolar RF energy from their electrode needle tips, thermally damaging surrounding tissue and stimulating a tissue healing process.	Microneedles are inserted into the dermis where they emit bipolar RF energy from their electrode needle tips, thermally damaging surrounding tissue and stimulating a tissue healing process.

**Level is defined by Intensity/Rate of Heating (Level 5 is equivalent to 9.58 W with a 300-ohm impedance)*
***Repetition Rate is defined as preset period between needle withdrawal and the next needle insertion*

Table 8-3: Comparison of parameters for Profound Matrix System's Sublative RF applicator and eTwo System's Sublative applicator

Specifications	Profound Matrix Sublative RF (Subject device)	eTwo Skin Treatment System Sublative RF K141507 (Reference Device #1)
Energy Type	RF	RF
Applicator Dimensions	15 x 16 cm / 5.9 x 6.3" [W x H]	15 x 16 cm / 5.9 x 6.3" [W x H]
Applicator Weight	0.5 kg. / 1.1 lbs.	0.5 kg. / 1.1 lbs.
RF Frequency	1 MHz	1 MHz
Power Range	14-55 W	14-55W
Treatment Area	64 pin Tip 12 x 12 mm -or- 44 pin Tip 3 x 11 mm	64 pin Tip 12 x 12 mm -or- 44 pin Tip 3 x 11 mm
Pulse Duration	Up to 500 ms	Up to 500 ms
Total RF Energy	Up to 100mJ/pin	Up to 100mJ/pin
Applicator Dimensions	15 x 16 cm	15 x 16 cm
Disposable Tip Matrix	44 or 64 matrix pins	44 or 64 matrix pins
RF Energy Penetration depth	Up to 400 µm	Up to 400 µm
Disposable Treatment Tip Lifetime	Up to 400 pulses	Up to 400 pulses
Rated Voltage	275 Vrms	275 Vrms
Mode of operation	During treatment, the multi-electrodepin array is placed on the dry skin's surface. The RF current flows betweenthe rows of the pins, having the highest impact at the electrode-skin contact points where it creates spots of demarcated ablation and resurfacing of the skin (stratum corneum, the deeper epidermis and superficial dermis) to achieve wrinkle treatment	During treatment, the multi-electrodepin array is placed on the dry skin's surface. The RF current flows betweenthe rows of the pins, having the highest impact at the electrode-skin contact points where it creates spots of demarcated ablation and resurfacing of the skin (stratum corneum, the deeper epidermis and superficial dermis) to achieve wrinkle treatment

Table 8-4: Comparison of parameters for Profound Matrix System's Sublime RF applicator and eTwo System's Sublime applicator

Specifications	Profound Matrix Sublime (Subject Device)	eTwo Skin Treatment System Sublime (Refirme) K141507 (Reference Device #1)
Energy Type	RF and IR	RF and IR
Applicator Dimensions	20 x 20 cm / 7.8 x 7.8" [W x H]	20 x 20 cm / 7.8 x 7.8" [W x H]
Applicator Weight	1.0 kg. / 2.2 lbs.	1.0 kg. / 2.2 lbs.
Frequency	1 MHz	1 MHz
RF Power	200 W (≤138.9 W/cm2)	200 W (≤138.9 W/cm2)
Treatment Area	8 x 12 mm	8 x 12 mm
Pulse Duration	Up to 200 ms	Up to 200 ms
Total RF Energy	Hz Mode: 50-200 J/cm3 Hz Mode: 50-100 J/cm3	Hz Mode: 50-200 J/cm3 Hz Mode: 50-100 J/cm3
Wavelength Spectrum	700 – 2000 nm	700 – 2000 nm
Optical Energy: Power	6 W/cm^2 ± 20%	6 W/cm^2 ± 20%
Light Pulse Duration	Up to 250 ms	Up to 250 ms
Rated Voltage	300 Vrms	300 Vrms
Mode of operation	RF combined with light energy heats the biological tissue in a controlled fashion for non-ablative therapeutic effects which trigger dermal tissue remodeling for the treatment of wrinkles. The physician adjusts the treatment parameters for the patient's treatment and the applicator is moved in a constant circular pattern for a further decrease of any potential heating damage to the skin.	RF combined with light energy heats the biological tissue in a controlled fashion for non-ablative therapeutic effects which trigger dermal tissue remodeling for the treatment of wrinkles. The physician adjusts the treatment parameters for the patient's treatment and the applicator is moved in a constant circular pattern for a further decrease of any potential heating damage to the skin.

9. PERFORMANCE DATA

The following performance data supports the substantial equivalence determination:

Electrical Safety and Electromagnetic Compatibility Standards

IEC 60601-1: Medical electrical equipment – Part 1: General requirements forbasic safety and essential performance

IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirementsfor safety –

collateral standard: electromagnetic compatibility (EMC)- requirements and test

IEC 60101-2-2: Particular requirements for the basic safety and essentialperformance of high frequency surgical equipment and high frequency surgical accessories.

Biocompatibility

The biocompatibility of the Profound Matrix System's patient contacting componentshas been established based on the predicate devices and the results of ISO 10993 testing.

Software Verification & Validation

Software verification and validation testing was conducted, and results were found tobe acceptable for software release. Software testing was performed per FDA's guidance document "Guidance for the Content of Premarket Submission for SoftwareContained in Medical Devices."

Bench Testing

Candela conducted additional bench testing, verification, and validation to assure that the Profound Matrix functions safely under the predefines specifications. Theadditional bench tests performed are as follows:

- Shelf-life and transportation testing
- Human factors summative usability
- Thermal testing in accordance with FDA's "Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Electrosurgical Devicesfor General Surgery," (March 9, 2020).
- Applicator cleaning and disinfecting validation in accordance with FDA's "Guidance for Industry and FDA Staff: Reprocessing Medical Devices in HealthCare Settings: Validation Methods and Labeling

Ex-Vivo Thermal Damage Evaluation Summary

Bench testing was performed on ex-vivo, excised abdominal skin tissue in order to evaluate the treatment effects from the Matrix Pro applicator and the predicate device, the Infini applicator, and to compare the effects of the two devices. Delivered RF energies for the Matrix Pro and the Lutronic Infini were designed to be similar. The samples were treated with four RF energy levels (1J, 2J, 3J and 4J) and included three treatment depths using two depth configurations (dense and spread).

Thermal effects from RF energy pulses were measured and found to be at the pulse depth setting for Matrix Pro (investigational device) and Lutronic Infini (primary predicate device). The thermal effects were found in similar depths following treatments with both devices. Similar widths (diameter of thermal impact) were measured following 1J Matrix Pro treatments and 3J and 4J Infini treatments. This may be explained by the lack of control

of energy levels with the Infini, where the Matrix.

Pro uses the impedance, calculated using the voltage and current during the procedure, to determine the pulse length. Thus, the device emits the precise amount of energy to the surrounding tissue that was selected by the end-user.

It was observed that the Lutronic Infini and the Matrix Pro produce similar thermal effects resulting from each device's bipolar RF microneedling: collagen denaturation consistent with tissue heating was observed in the dermis (i.e., the target tissue) voids consistent with broken fat cells membranes and a surrounding layer of compressed fat cells were observed in the fat layer.

Animal and Clinical Testing

Based on the similarities of the device specifications, intended use, indications for use between the Profound Matrix and its predicate device, no clinical or animal studies were needed to support this 510(k) Premarket Notification.

10. STATEMENT OF SAFETY AND EFFECTIVENESS

The Profound Matrix shares a similar design and intended use to its predicate (K121481). Additionally, principles of operation, performance characteristics, technological characteristics are similar between the Profound Matrix System and its predicate devices. The results of verification and validation activities, i.e., testing to standards and performance testing of the devices, have demonstrated substantial equivalence of the Profound Matrix to its predicate devices. The minor differences in the Profound Matrix System do not raise new types of questions regarding safety andefficacy, and the data presented in this 510(k) Premarket Notification supports the contention that the device is substantially equivalent to the predicate device.