July 1, 2024

Candela Corporation
Rina Ordonez
Sr. Regulatory Affairs Specialist
251 Locke Drive
Marlborough, Massachusetts 01752

Re: K240070
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: January 9, 2024
Received: May 23, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.07.01 18:56:13 -04'00'

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)*
K240070

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 Matrix Pro applicator is indicated for the percutaneous treatment of facial wrinkles in patients with Fitzpatrick Skin Types I-IV.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K240070
Profound Matrix System

This 510(k) Summary is being submitted in accordance with requirement 21CFR § 807.92.

1. General Information

January 9, 2024

Applicant

Candela Corporation

251 Locke Drive Marlborough MA 01752 USA

Contact Person

Rina Ordonez
Senior Regulatory Affairs Specialist
Candela Corporation
251 Locke Dr.
Marlborough, MA 01752
Office: 508-834-6072
Email: rinao@candelamedical.com

2. Device Information

Proprietary Name/Trade Name:	Matrix™, 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

3. Predicate Device

Primary Predicate: Lutronic Infini (K121481)
Reference Predicate Device: Profound Matrix (K211217)

4. Device Description

Profound Matrix is a system that 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.

Console

The system console consists of a CPU, power supply, RF pulse generator, I/O board, splitter/distribution board and footswitch board. When the system is powered up, the user can select between user mode and service/maintenance mode. After selecting user mode and entering the required password, the user is requested to choose between the Matrix Pro, the Sublative RF or the Sublime applicators. Only one applicator can be used to treat a patient at any given time.

The user interfaces with the Profound Matrix System and applicators' settings through the 15" touch screen. Each of the applicators have a finger trigger that can be used to activate the applicator or alternatively the end user can use the footswitch to activate the applicator.

Applicators

Matrix Pro

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 up to a maximum of three depths during each insertion of the matrix/grid of microneedles with a maximum depth of up to 3.5mm.

The Matrix Pro applicator delivers the right amount of energy at the precise depth, every time. The technology of the Matrix Pro applicator combines adjustable depth, energy, and real time impedance monitoring for customizable and consistent results. The Profound Matrix system monitors tissue impedance across the 3 modalities, in real-time, while simultaneously adjusting RF energy pulse duration and power output. The result is an accurate dose of RF energy delivery with every treatment application for consistent treatment outcomes, independent of patient-to-patient, body location, skin hydration, and procedural-related impedance variations.

Sublative RF

The Sublative RF applicator delivers bipolar radiofrequency (RF) to the skin surface in a fractional manner viaan array of multi-electrode pin tips, which results in heating of both the demarcated spots to temperatures that ablate and resurface at contact points of the multi-electrode pins while also delivering heat in a wide diffuse manner to the dermis.

Sublime

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.

5. Indications 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 Matrix Pro applicator is indicated for the percutaneous treatment of facial wrinkles in patients with Fitzpatrick Skin Types I-IV.

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 higher energy levels greater than 100 J/cm^3, the Sublime applicator is limited to Fitzpatrick skin types I-IV.

6. New indication for use for the Matrix Pro

The Matrix Pro applicator is newly intended for the percutaneous treatment of facial wrinkles in patients with Fitzpatrick Skin Types I-IV. This new indication is supported by comparison of the subject device with the predicate and reference devices that demonstrate comparability in technical functionality, safety performance, and intended use (illustrated in the Table below), and through the provision of retrospective study clinical and safety data that supports the safety and efficacy of application of the subject device for the new intended use to the intended patient population.

Type **510(k)** **Device Name** **Company Name**	**Subject Device** **K240070** **Matrix Pro – Profound Matrix** **Candela Corporation**	**Predicate Device** **K121481** **Infini RF system** **Lutronic Inc.**	**Reference Predicate Device** **K211217** **Matrix Pro - Profound Matrix** **Candela Corporation**
Product code	GEI-Electrosurgical, Cutting & Coagulation & Accessories	GEI-Electrosurgical, Cutting & Coagulation & Accessories	GEI-Electrosurgical, Cutting & Coagulation & Accessories
Indications 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 Matrix Pro applicator is indicated for the percutaneous treatment of facial wrinkles in patients with Fitzpatrick Skin Types I-IV.** 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/cm^3, the Sublime applicator is limited to Fitzpatrick Skin Types I-IV.	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 **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/cm^3, the Sublime applicator is limited to Fitzpatrick Skin Types I-IV.

7. Intended Use / Indication For Use Comparison

The subject device, Matrix Pro, and its predicate device, Infini (K121481), have similar technical configurations and indications for use, both are intended to be used for not just general dermatological procedures for electrocoagulation and hemostasis but also for percutaneous facial wrinkles. Candela Corporation has performed clinical studies to support the wrinkles indications for use and the results of the studies can be found in the clinical section of this submission, demonstrating no new questions of safety or efficacy.

8. Technological Specifications Comparison

The subject device Matrix Pro applicator for Profound Matrix system shares with the predicate device Infini (K121481) the same underlying technology and presents similar intended use.

Both Matrix Pro and predicate devices use radiofrequency as their energy source with microneedles delivered to the skin. Both have the same main functional components consisting of a system console with a user interface.

The subject device is substantially equivalent to the predicate devices with respect to hardware and software, principle of operation and product design.

Any differences do not raise any new concerns for safety or efficacy, Matrix Pro has been tested and has completed a clinical study on the proposed indication that demonstrated the device's ability to meet the wrinkle endpoint.

9. Performance Data

The Profound Matrix has been thoroughly evaluated for electrical safety. The device has been found to comply with applicable medical device safety standards.

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.

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

10. Clinical Performance

A retrospective analysis of subject data was conducted to demonstrate the safety, efficacy, tolerability, and usability of the Matrix Pro Applicator for the treatment of wrinkles. The FUFT2002 source study, sponsored by Candela Medical, the manufacturer of the Profound Matrix System™, was a multi-site prospective clinical trial.

The retrospective analysis comprised data from 32 healthy subjects, aged 25-70 years, with Fitzpatrick Skin Types II-IV who received up to 3 full-face treatment for wrinkles with the Matrix Pro Applicator (27W) and returned for follow-ups 1- and 3- months after last treatment. A total of 92 treatments were conducted during the study, with treatments administered at depths ranging from 0.8 to 3.5 mm and 0.5 to 4.0 J pulse energy.

Primary efficacy endpoint was assessed by blinded evaluators comparing photographs taken at Baseline and at 3-month follow-up (3MFU) presented in randomized de-identified order. Treatment was considered a success if at least 2 of 3 blinded reviewers correctly identified the post-treatment photograph based on the appearance of wrinkles. Blinded reviewers correctly identified post-treatment photographs for 75% of subjects (24 of 32), surpassing the study's pre-determined success criteria of 70%. Post-hoc assessment of the primary outcome was also performed defining an individual subject responder as a participant whose after photos were rated at least 1 point improved on the validated Fitzpatrick Wrinkle and Elastosis Scale (FWES) by at least two of three blinded reviewers. 62.5% (20 of 32) of subjects were responders under this criteria. Additionally, the mean change (improvement) in combined blinded evaluator FWES ratings from baseline to 3 Months Follow-Up assessment was found to be statistically significant ($p<0.005$).

Additionally, subjects were asked to rate their perceived improvement in the overall appearance of their face after receiving the treatments with the Matrix Pro Applicator according to the 5-point Global Aesthetic Improvement Scale. At 1MFU, 91% reported that their overall facial appearance had 'improved' following the treatments with the Matrix Pro Applicator, with 41% reporting this improvement as 'much improved' or 'very much improved'. By 3MFU, 94% of subjects rated their overall facial appearance as having improved, with those reporting this improvement as 'much improved' or 'very much improved' also increasing notably from 41% to 53%.

Treatments were tolerated well with a mean pain score of 4.7 (± 1.67) on an 11-point Numerical Rating Scale (0=no pain to 10=worst pain). Mild to moderate edema, erythema, and pinpoint bleeding were common and anticipated immediate post-treatment responses, all of which resolved in a reasonable timeframe. Four possibly related adverse events occurred for subjects in the study, with three determined to be mild in nature, requiring minimal intervention, each fully resolving before study end, and none requiring the subject to be withdrawn from continued participation in the study. There were no serious or unanticipated adverse events during the study.

The findings from the retrospective study are highly supportive of the positive device treatment effect in the clinically meaningful reduction of wrinkles and supports a determination of substantial equivalence, as the efficacy and safety outcomes presented are comparable to or exceed those reported for other clinical trials whose results have successfully supported prior FDA clearances for comparable indications for use for comparable devices.

The Profound Matrix System with the Matrix Pro Applicator demonstrated both efficacy and safety in the treatment of facial wrinkles for patients with Fitzpatrick Skin Types I-IV. The balance of risks and benefits is favorable, with demonstrated significant and clinically meaningful improvements in wrinkle appearance and positive subject satisfaction, alongside a favorable safety profile, indicating the device treatment as a viable and beneficial option for individuals seeking dermatological solutions for facial wrinkles for patients with Fitzpatrick Skin Types I-IV.

11. Conclusion

The Matrix Pro applicator shares the same technological characteristics, mechanism of action, and functionality, as the reference device (K211217). The only difference between the subject and predicate device is the addition of the new intended indication for use which is additionally shared by the predicate device, Lutronic's Infini (K121481). The Matrix Pro applicator device's ability to safely and efficaciously perform under the new intended use has been confirmed by the results provided from the retrospective study analysis. The study revealed that there were no issues that

would raise new or different questions of safety or effectiveness and given that clinically meaningful efficacy in the absence of serious adverse events was found, the benefits of the Matrix Pro applicator outweigh the risks of the device for its new intended use. Additionally, the retrospective study data further supported that the subject device performs as intended and in accordance with its specifications. Therefore, it is concluded that the Matrix Pro applicator has been shown to be safe and effective for its new intended use and substantially equivalent to the currently cleared predicate and reference devices.