February 2, 2021

Pulse Biosciences, Inc.
William Knape
VP Regulatory, Clinical, & Quality Affairs
3957 Point Eden Way
Hayward, California 94545

Re: K203299
Trade/Device Name: CellFX® System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 6, 2020
Received: November 9, 2020

Dear William Knape:

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)*
K203299

Device Name
CellFX® System

Indications for Use *(Describe)*
The CellFX® System is intended for dermatological procedures requiring ablation and resurfacing of the skin.

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.

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510(k) Summary

I. Submitter

Applicant: Pulse Biosciences, Inc.
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Hayward, CA 94545
Phone: (510) 906-4649

Contact Person: William A. Knape
VP Regulatory, Clinical, & Quality Affairs
Pulse Biosciences, Inc.
Phone: (919) 757-2033

Date Prepared: February 2, 2021

II. DEVICE INFORMATION

Trade Name: CellFX® System

Regulation Number: 21 CFR § 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Class: Class II
Product Code: GEI
Classification Panel: General and Plastic Surgery

III. PREDICATE DEVICE

K102461 – Fractora by Invasix Ltd.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Pulse Biosciences® CellFX® System is a proprietary platform technology. The CellFX System consists of the CellFX Console, CellFX Handpiece, CellFX Treatment Tips, and CellFX Software. The CellFX System delivers nanosecond duration electrical pulses that disrupt the function of cells leading to cell death, while sparing non-cellular tissue. The CellFX System delivers a series of timed, nanosecond electrical pulses (referred to as a "Cycle") to ablate and resurface tissue areas in dermatologic conditions.

The CellFX Console is capable of delivering short electric pulses at amplitudes up to 15 kV and pulse widths up to 700 ns. The electrical energy pulses are applied directly to targeted tissue using sterile Treatment Tips with stainless steel microneedles. The

treatment parameters are selected by the user through a user interface on the Touchscreen Display of the CellFX Console.

V. INDICATIONS FOR USE STATEMENT

The CellFX® System is intended for dermatological procedures requiring ablation and resurfacing of the skin.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

To support a determination of substantial equivalence, Pulse Biosciences performed verification and validation testing demonstrating the subject device performs as intended; thus, even though the CellFX System has different technological characteristics than the predicate device, the differences do not raise new or different questions of safety and effectiveness.

	Subject Device	Predicate Device (K102461)
Trade Name	CellFX® System	Fractora
Prescription Only	Yes	Yes
Regulation Number	878.4400	878.4400
Product Code	GEI	GEI
Indications for Use		
Indications for Use Statement	The CellFX System is intended for dermatological procedures requiring ablation and resurfacing of the skin.	Fractora is intended for dermatological procedures requiring ablation and resurfacing of the skin.
Technological Characteristics		
Mechanism of Action	Nano-Pulse Stimulation: ultrafast nanosecond electrical pulses to the targeted tissue via treatment tips with an array of microneedles	Non-homogeneous (fractional) pulsed RF energy delivered to skin via an array of multi-electrode pins resulting in heating of skin directly below the electrodes
Pulse Frequency	1-10 Pulses per second	Up to 2 Pulses per second
Pulse Amplitude/Voltage	300V to 15kV	~300 Volts
Pulse Width	100 ns – 700 ns	Not Applicable
Power Input	100-240 VAC, 50/60 Hz, 2A	100-240 VAC, 50-60 Hz, 1.4 A
Power Output	30 Watts	75 Watts
Energy Range	Minimum: 0.5 Joules @ 0.06 Watts Maximum: 4.3 Joules @ 0.6 Watts	Minimum: 0.2 Joules @ 75 Watts Maximum: 3.7 Joules @ 75 Watts
Integrated Skin Temperature Sensor	Not Included	Included
Use of Local Anesthesia	Yes	Yes
Treatment Tip	Yes	Yes
Handpiece	Yes	Yes

System Physical Characteristics		
Height	132 cm	100 cm
Length	46 cm	36 cm
Width	53 cm	36 cm
Weight	54 kg	15 kg
Power Input	100-240 VAC, 50/60 Hz, 2A	100-240 VAC, 50-60 Hz, 1.4 A
Tip Characteristics		
Microneedle Configuration	1.5x1.5mm: 2 rows of 3 pins per row 2.5x2.5mm: 2 rows of 3 pins per row 5.0x5.0mm: 2 rows of 4 pins per row	24 pin tip: 6 rows of 4 pins per row 60 pin tip: 10 rows of 6 pins per row

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The testing was conducted in accordance with FDA Guidance, issued June 16, 2016: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process." All biocompatibility tests met their respective acceptance criteria.

The battery of testing included the following:

- Material-Mediated Pyrogenicity
- Systemic Toxicity
- Sensitization
- Irritation
- Cytotoxicity
- Hemolysis

All biocompatibility tests met their respective acceptance criteria.

Electrical safety and electromagnetic compatibility (EMC)

The CellFX System complies with IEC 60601-1, IEC 60601-1-2, 60601-2-2, IEC 60601-1-6, IEC 62366, and IEC 62304. All test conditions were performed as outlined within the IEC standards. All electrical safety and EMC tests passed

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern since a failure of the device could directly result in minor injury to the patient or operator. Completed software testing supports the safety and effectiveness of the device.

Cybersecurity controls have been implemented to mitigate the risk of malware being introduced into the CellFX System as recommended by FDA's Draft Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."

Animal Study

A GLP animal safety study was conducted to validate the safety and performance of the CellFX System. The study was conducted on 15 Yucatan pigs that underwent skin treatments with either the CellFX System (test) or the predicate device (control). Animals were divided into 5 cohorts of 3 animals each for the following timepoints: 0, 2, 6, 14, and 30-days.

Safety

- All animals survived to their termination date with no procedure related complications. Based on the results of intra-procedural treatments, gross evaluation, histopathological analysis, clinical pathology, and in-life physical examinations the CellFX treatments are considered to be safe.

Performance

- All test articles met the acceptance criteria for device performance. The treatment zones met the acceptance criteria. The CellFX treatment sites successfully achieved degeneration and necrosis of active treatment sites while the epidermis remained intact. The device is expected to perform as intended.

Summary

Based on the GLP animal safety study, the CellFX System was found to have a safety and performance profile that is equivalent to the predicate device.

CONCLUSION

The CellFX® System has the same intended use as the predicate. The differences in technological characteristics between the CellFX System and predicate device do not raise any different questions of safety and effectiveness. The non-clinical performance testing and *in vivo* animal data provided in this submission demonstrate and support that the CellFX System is as safe and as effective as the predicate device. Therefore, the CellFX System is substantially equivalent to the predicate device.