September 22, 2022

Pulse Biosciences, Inc.
Punam Gollamudi
Director US Regulatory Affairs
3957 Point Eden Way
Hayward, California 94545

Re: K213674
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: August 25, 2022
Received: August 26, 2022

Dear Punam Gollamudi:

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,

for

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)*
K213674

Device Name
CellFX® System

Indications for Use *(Describe)*

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

Specific Indication: The CellFX System with the CellFX Treatment Tip 2.5mm is indicated for the treatment of sebaceous hyperplasia (SH) in patients with Fitzpatrick skin types I-III.

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. 3957 Point Eden Way Hayward, CA 94545 Phone: (510) 906-4649
Contact Person:	Punam Gollamudi Director of US Regulatory Affairs Pulse Biosciences, Inc. Phone: (415) 305-4404
Date Prepared:	September 19, 2022

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

K211444 – CellFX® System, Pulse Biosciences, Inc.
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 delivers 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 indicated for dermatological procedures requiring ablation and resurfacing of the skin.

Specific Indication: The CellFX System with the CellFX Treatment Tip 2.5mm is indicated for the treatment of sebaceous hyperplasia (SH) in patients with Fitzpatrick skin types I-III.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device has the same technological characteristics as the predicate device. The device design, materials, fundamental scientific technology, materials and processes for packaging and sterilization have not been changed from the predicate device.

	Subject Device	**Predicate Device (K211444)**
Trade Name	CellFX® System	CellFX® System
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 indicated for dermatological procedures requiring ablation and resurfacing of the skin. Specific Indication: The CellFX System with the CellFX Treatment Tip 2.5mm is indicated for the treatment of sebaceous hyperplasia (SH) in patients with Fitzpatrick skin types I-III.	The CellFX System is intended for dermatological procedures requiring ablation and resurfacing of the skin.

	Subject Device	Predicate Device (K211444)
Technological Characteristics		
Mechanism of Action	Nano-Pulse Stimulation: ultrafast nanosecond electrical pulses to the targeted tissue via treatment tips with an array of microneedles	Nano-Pulse Stimulation: ultrafast nanosecond electrical pulses to the targeted tissue via treatment tips with an array of microneedles
Pulse Frequency	1 Hz -10 Hz	1 Hz -10 Hz
Pulse Amplitude/Voltage	300V to 15kV	300V to 15kV
Pulse Width	100 ns – 700 ns	100 ns – 700 ns
Power Input	100-240 VAC, 50/60 Hz, 2A	100-240 VAC, 50/60 Hz, 2A
Power Output	30 Watts	30 Watts
Energy Density Range	2.5 x 2.5 mm – 30-60 mJ/mm^3	1.5 x 1.5 mm – 110-190 mJ/mm^3 2.5 x 2.5 mm – 60-110 mJ/mm^3 5.0 x 5.0 mm – 45-85 mJ/mm^3
Use of Local Anesthesia	Yes	Yes
Sterile Tip	EO Sterilization	EO Sterilization
Handpiece	Single Handpiece for 2-Row Tips	Single Handpiece for 2-Row Tips
System Physical Characteristics		
Height	132 cm	132 cm
Length	46 cm	46 cm
Width	53 cm	53 cm
Weight	54 kg	54 kg
Power Input	100-240 VAC, 50/60 Hz, 2A	100-240 VAC, 50/60 Hz, 2A
Tip Characteristics		
Treatment Tip	2-Row	2-Row
Microneedle Configuration		
1.5 x 1.5 mm 2.5 x 2.5 mm 5.0 x 5.0 mm	N/A 2 rows of 3 or 4 needles per row N/A	2 rows of 3 needles per row 2 rows of 3 or 4 needles per row 2 rows of 4 or 6 needles per row
Tip Insertion Depth	1 mm and 2 mm	1 mm and 2 mm

VII. PERFORMANCE DATA

The following performance data was referenced or provided in support of the substantial equivalence determination.

Biocompatibility Testing
Biocompatibility testing was not required as there were no changes to the device compared to the predicate.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing was not required as there were no changes to the device compared to the predicate.

Bench Testing
Performance testing was not required as there were no changes to the device compared to the predicate.

Software Verification and Validation Testing
Software verification and validation testing was not required as there were no changes to the device compared to the predicate.

Animal Study

Animal testing was not required to support the change to the Indications for Use.

Clinical Study

A prospective, multi-center, randomized, comparison clinical study was conducted to support safety and effectiveness of the CellFX System for the treatment of sebaceous hyperplasia (SH). A total of 59 subjects treated with the 2.5mm Tip were mostly female (79.7%) and white (91.5%). All treatments were performed at a depth of 2mm on subjects with Fitzpatrick skin types I-III. A total of 121 SH lesions were randomized to the CellFX System and 107 to Electrodessication in a split-face study design.

Safety Endpoints

The study was designed to evaluate co-primary safety and effectiveness endpoints. The first primary safety endpoint of lesions showing hyperpigmentation and scarring and assessed by the blinded Investigator at 60 days after the last treatment demonstrated CellFX to be non-inferior to Electrodessication. This safety endpoint found with 19.2% of lesions treated with CellFX and 12.1% of lesions treated with electrodessication having pigmentary changes or scarring. The second co-primary safety endpoint of skin textural changes (crusting, flaking, or other skin textural changes) as assessed by the blinded Investigator at 30 days after the last treatment showed rates of 6.8% of lesions treated with CellFX and 10.3% of lesions treated with Electrodessication.

Effectiveness Endpoint

The primary effectiveness endpoint of improvement at 60-days post-last treatment as assessed "live" by the blinded site investigator using the 5-point GAIS (1 = much worse, 2 = worse, 3 = no change, 4 = improved, 5 = much improved, with scores of 4 or 5 classified as responders) showed rates of aesthetic appearance to be improved or much improved for 76.9% of lesions treated with CellFX and 75.5% of lesions treated with electrodessication.

Adverse Events

There were 3 (2.5%, n=120) treatment-related non-serious adverse events (AEs) in 3 subjects with mild swelling at the lesion site treated with the CellFX 2.5mm treatment tip. None of the events required medical intervention and all resolved by the 7-day follow-up visit. One subject was instructed to use ice for swelling.

Summary

Evaluation of primary safety and effectiveness endpoints showed CellFX to be non-inferior to Electrodessication. Adverse events associated with the procedure were relatively mild, transient, and not unexpected for this type of procedure, demonstrating that the risks associated with CellFX and procedure are minimal. There were no device-related adverse events and no unanticipated adverse events. The clinical study demonstrated that the CellFX System using the CellFX Treatment Tip 2.5mm was safe and effective for the treatment of sebaceous hyperplasia (SH).

CONCLUSION

The CellFX System has the same intended use, technological characteristics and principles of operation and similar indications for use as its predicate device. Clinical studies of the CellFX System have demonstrated the safety and effectiveness profile of the device in the intended population. Thus, the CellFX System is substantially equivalent to the predicate device.