March 8, 2024

Pulse Biosciences, Inc.
Uyen Mai
Director, Regulatory Affairs, Quality Assurance, and Quality Control
3957 Point Eden Way
Hayward, California 94545

Re: K233705
Trade/Device Name: CellFX Percutaneous Electrode System (SYS3000)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 2, 2024
Received: February 5, 2024

Dear Uyen Mai:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.03.08 12:47:48 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K233705

Device Name
CellFX Percutaneous Electrode System (SYS3000)

Indications for Use *(Describe)*
The CellFX Percutaneous Electrode System is intended for ablation of soft tissue in percutaneous and intraoperative surgical procedures.

The CellFX Percutaneous Electrode System (Percutaneous Electrode) is not intended for use in cardiac procedures.

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: (833) 257-3393

Contact Person: Uyen Mai, MS
Director, Regulatory Affairs, QA and QC
Pulse Biosciences, Inc.
Phone: (510) 906-4691

Date Prepared: November 16, 2023

II. DEVICE INFORMATION

Trade Name: CellFX® Percutaneous Electrode 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

K190052 – Surgnova Healthcare Technologies (Zhejiang) Co., Ltd, Radio Frequency Ablation System

Reference Devices K052796 - Valleylab Cool-tip RF Ablation System and K203299 – CellFX System

IV. DEVICE DESCRIPTION

The CellFX® Percutaneous Electrode System includes the CellFX Console, CellFX Percutaneous Electrode and Accessories: Percutaneous Adapter, pneumatic footswitch, and system software. The CellFX® Console is a proprietary energy-based platform for nanosecond Pulsed Field Ablation™ (nsPFA™) technology. nsPFA is a cell-specific, nonthermal ablation technology that delivers nanosecond-duration pulses of high-amplitude electrical energy to tissue via bipolar electrodes. The pulses create nanopores in lipid membranes, which disrupt the ability of the cell and internal organelles to maintain cellular homeostasis – ultimately leading to regulated cell death (e.g., apoptosis). The electrode is provided sterile, for single use only.

V. INDICATIONS FOR USE STATEMENT

The CellFX® Percutaneous Electrode System is intended for ablation of soft tissue in percutaneous and intraoperative surgical procedures. It is not intended for use in cardiac procedures.

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; therefore, even though the CellFX Percutaneous Electrode System has different technological characteristics than the predicate device, based on the data provided, the CellFX Percutaneous Electrode System does not raise any new or different questions of safety and effectiveness.

	Subject Device	**Predicate Device (K190052)**	**Ref Device (K052796)**	**Ref Device (K203299)**
Trade Name	CellFX® Percutaneous Electrode System	Dolphi RF R150E Ablation System	Valleylab Cool-tip RF Ablation System	CellFX System
Prescription Only	Yes	Yes	Yes	Yes
Regulation	878.4400	878.4400	878.4400	878.4400
Product Code	GEI	GEI	GEI	GEI
Indications for Use				
Indications for Use Statement	Intended for ablation of soft tissue in percutaneous and intraoperative surgical procedures. It is not intended for use in cardiac procedures.	Intended for coagulation and ablation of soft tissue. It is not intended for use in cardiac procedures.	Intended for the use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of tissue.	Intended for ablation and resurfacing of the skin.
Technological Characteristics				
Components	RF Generator, Active Electrode, Adapter, Footswitch	Radio Frequency Generator, Radio Frequency Electrode Kits, Temperature Probe, and Foot Switch	RF Generator, peristaltic pump, electrodes, inflow/outflow tubing, and return pads	RF Generator, Handpiece, Treatment tips
Mechanism of Action	Nanosecond Pulse Field Ablation (nsPFA): ultrafast nanosecond electrical	Radiofrequency current for ablation of soft target tissue	Radiofrequency current for ablation of soft target tissue	Same as Subject Device

	Subject Device	Predicate Device (K190052)	Ref Device (K052796)	Ref Device (K203299)
	pulses to the targeted tissue			
Output Frequency	1-10 Pulses per second	470kHz	480kHz±10%	Same as Subject Device
Pulse Amplitude/Voltage	800V to 15kV	Up to 200 watts @50 ohm	Up to 200 watts @50 ohm	Same as Subject Device
Pulse Width	100 ns – 500 ns	N/A	N/A	Same as Subject Device
Power Input	100-240 VAC, 50/60 Hz, 2A	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	Same as Subject Device
Max Power Output	15 Watts (when pulsing at 15kV pulse voltage with 500 ns pulse width and 10 Hz pulse frequency into a 75 Ohm load)	Up to 200 Watts@50 ohms	0-200 watts max output @ 50 ohm load	Same as Subject Device
Active Electrodes				
Energy Output	Bipolar RF	Monopolar RF	Monopolar RF	Same as Subject Device
Electrode Length (mm)	95	70, 150, 200, 250	100, 144, 150, 200, 250	Same as Subject Device
Exposure Length (mm)	14	5, 7, 10, 15, 20, 30, 40	7, 10, 20, 30	Same as Subject Device
Outer Diameter (mm)	2.4	1.2, 1.47	1.2	Same as Subject Device
Tip Type	Trocar	Trocar	Trocar	Microneedle Array
Material	Stainless Steel 304	Stainless Steel 304	Stainless Steel 304	Same as Subject Device
Disposable/Singe - Use Device	Single-Use	Single-Use	Single-Use	Same as Subject Device

	Subject Device	Predicate Device (K190052)	Ref Device (K052796)	Ref Device (K203299)
Biocompatibility	Patient-contacting materials are biocompatible	Patient-contacting materials are biocompatible	Patient-contacting materials are biocompatible	Same as Subject Device
Sterility	EO Sterilization	EO Sterilization	EO sterilization	Same as Subject Device
System Physical Characteristics				
Voltage Supply	100-240 VAC, 50/60 Hz, 2A	100-240 VAC, 50/60 Hz, 2A	100-240 VAC, 50/60 Hz, 2A	Same as Subject Device

VII. PERFORMANCE DATA

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

Biocompatibility Testing

The testing was conducted in accordance with FDA Guidance, issued September 4, 2020: 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, for each of the following tests:

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

The biocompatibility test results successfully demonstrate biocompatibility of the CellFX Percutaneous Electrode.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing

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.

Bench Testing

The performance bench testing was conducted to ensure that the CellFX Percutaneous Electrode System performs as intended per its specifications.

Software Verification and Validation Testing

Software verification and validation testing were conducted and enhanced documentation was provided as recommended by FDA's Guidance, "Content of Premarket Submissions for Device Software Functions," issued on June 14, 2023. The intended use of this device is for general surgical procedures and in accordance with FDA's Guidance, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery," issued on March 9, 2020, an enhanced documentation level of software testing was included in this 510(k) that supports the safety and effectiveness of the device.

Cybersecurity controls have been implemented to mitigate the risk of malware being introduced into the CellFX Percutaneous Electrode System as recommended by FDA's Guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," issued on September 27, 2023

Pre-Clinical Animal Safety and Performance Studies

In accordance with FDA's Guidance, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery," two *in vivo* animal studies were conducted to support the safety and performance of the CellFX Percutaneous Electrode System. Based on the *in vivo* animal safety studies, the data provided in this submission demonstrates and supports that the CellFX Percutaneous Electrode System is safe and effective for ablation of soft tissue and is substantially equivalent to the predicate device.

Human Safety Study

A prospective single-arm clinical study of ten (10) subjects was completed to demonstrate safety and effectiveness of the CellFX Percutaneous Electrode System. Two to four ablation zones were completed in benign thyroid nodules under ultrasound guidance and subjects were followed at 30 and 90 days post-treatment. Subjects showed an average of 95% reduction in ablation zones by 30 days. No serious adverse events were observed. Overall, the findings of this study provided strong evidence of the safety and effectiveness of the system in a surgical application in soft tissue.

Summary

The performance testing in pre-clinical and clinical safety studies was conducted to ensure that the CellFX Percutaneous Electrode System performs as intended per its specifications. CellFX Percutaneous Electrode System treatments are deemed non-thermal and did not result in any safety concerns during its intended use. Therefore, the performance testing verified that the device performs as intended and that the tested energy settings and treatment profile in soft tissue does not raise any different questions of safety or effectiveness.

VIII. CONCLUSION

The CellFX® Percutaneous Electrode System has the same indication for use, technological characteristics and principles of operation as the predicate device. The non-clinical performance testing, *in vivo* animal data, and clinical performance study data provided in this submission demonstrate and support that the CellFX Percutaneous Electrode System performs as intended and is as safe and as effective as the predicate device. Therefore, the CellFX Percutaneous Electrode System is substantially equivalent to the predicate device.