UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): **January 2, 2024**

Pulse Biosciences, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-37744**	**46-5696597**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3957 Point Eden Way
Hayward, California 94545
(Address of Principal Executive Offices) (Zip Code)

510-906-4600
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, If Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common stock, $0.001 par value per share	PLSE	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On January 2, 2024, Pulse Biosciences, Inc. (the "Company") issued a press release announcing the filing of a premarket notification 510(k) to the U.S. Food and Drug Administration for its novel CellFX® nsPFA™ Cardiac Clamp. A copy of the Company's press release is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release issued by Pulse Biosciences, Inc. dated January 2, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PULSE BIOSCIENCES, INC.

Date: January 2, 2024

By: /s/ Kevin P. Danahy
Kevin P. Danahy
President and Chief Executive Officer
(Principal Executive and Principal Financial Officer)

Pulse Biosciences Files 510(k) Submission with U.S. FDA for its CellFX® nsPFA™ Cardiac Clamp

HAYWARD, Calif. [Business Wire] – January 02, 2024. Pulse Biosciences, Inc. (Nasdaq: PLSE), a company primarily focused on leveraging its novel and proprietary CellFX Nanosecond Pulsed Field Ablation (nsPFA) technology for the treatment of atrial fibrillation, today announced the filing of a premarket notification 510(k) to the U.S. Food and Drug Administration (FDA) for its novel CellFX nsPFA Cardiac Clamp.

Pursuant to Section 510(k), once the application has been accepted, the FDA will conduct its substantive review and may request additional information from the Company based on that review. FDA guidance suggests the goal is to complete 510(k) review within 90 calendar days, not including time required by the Company to respond to additional information requests. The time required to respond to any such requests will depend on the nature of the request.

“The comparative preclinical data included in this 510(k) submission clearly demonstrates the highly differentiated safety and performance benefits of nsPFA in cardiac ablation and its potential benefit to patients and physicians. The speed and precision of delivery and the quality of the lesions, independent of tissue type or thickness, along with the impressive safety profile are unique, and I expect will drive many cardiac surgeons like me to start utilizing the CellFX nsPFA Cardiac Clamp for their patients,” said Dr. Niv Ad, Chief Science Officer, Cardiac Surgery of Pulse Biosciences. “We look forward to sharing the preclinical dataset in upcoming scientific meetings and to collaborating with the FDA throughout its review process as we advance the clamp towards clinical use.”

Pulse Biosciences’ CellFX nsPFA Cardiac Clamp is designed to produce continuous linear transmural ablations during concomitant cardiac surgical procedures using the Company’s novel CellFX system. The bipolar clamp utilizes the Company’s proprietary nsPFA technology, a nonthermal ablation technology, and preclinical data suggest nsPFA may provide safety and performance benefits over the current thermal ablation technologies for cardiac ablation, such as the use of extreme heat or cold. A single CellFX nsPFA Cardiac Clamp ablation can be done in one-twentieth of the time of current thermal ablation technologies and, due to the nonthermal mechanism of action, does not have the risk of thermal spread leading to unintended collateral damage to adjacent tissue and structures.

“In my professional opinion, with FDA and worldwide regulatory clearance, the CellFX nsPFA Cardiac Clamp may become the gold standard in cardiac ablation for cardiothoracic surgeons. The consistency of continuous transmural ablations in a fraction of the time it takes for current radiofrequency or cryothermal ablation devices, combined with the safety benefits of nsPFA's nonthermal mechanism of action, may well be rapidly adopted by cardiothoracic surgeons like myself that perform cardiac ablations routinely, ” said Dr. Gan Dunnington, Chief Medical Officer, Cardiac Surgery of Pulse Biosciences. “The CellFX nsPFA Cardiac Clamp is designed to seamlessly replace current radiofrequency ablation devices, and based on the promising preclinical data we have in hand, we believe CellFX nsPFA has the potential to both expand adoption and increase procedure effectiveness, procedure volume and significant clinical use.”

“We are beyond excited to start 2024 with another milestone in the Company’s progress into the cardiac market. We expect the CellFX nsPFA Cardiac Clamp will demonstrate the superior safety and effectiveness of nsPFA for cardiac ablation in cardiac surgery and will serve as an entry point into this large and growing market. Along with our CellFX nsPFA 360 Cardiac Catheter, we plan to surround cardiac care teams with next generation nsPFA technology to drive better patient outcomes,” said Kevin Danahy, President and Chief Executive Officer of Pulse Biosciences.

About Pulse Biosciences®
Pulse Biosciences is a novel bioelectric medicine company committed to health innovation that has the potential to improve the quality of life for patients. The Company’s proprietary CellFX Nanosecond Pulsed Field Ablation (nsPFA) technology delivers nanosecond pulses of electrical energy to non-thermally clear cells while sparing adjacent noncellular tissue. The Company is actively pursuing the development of its CellFX nsPFA technology for use in the treatment of atrial fibrillation and in a select few other markets where CellFX nsPFA could have a profound positive impact on healthcare for both patients and providers.

Forward-Looking Statements
All statements in this press release that are not historical are forward-looking statements, including, among other things, statements relating to the effectiveness of the Company’s CellFX nsPFA technology and CellFX System to non-thermally clear cells while sparing adjacent non-cellular tissue and to have a consistent effect on the heart independent of tissue type or thickness, statements concerning the Company’s expected product development efforts, such as advancement of its cardiac clamp to treat atrial fibrillation, whether in one-twentieth of the time of current thermal ablation technologies or otherwise, statements concerning the Company’s future clinical and regulatory strategies and possible government clearances and approvals, statements concerning whether any clinical study will show that the Company’s novel nsPFA mechanism of action and clamp design will deliver fast and precise ablations in thick cardiac tissue, statements concerning market opportunities, customer adoption and future use of the CellFX System to address a range of conditions such as atrial fibrillation, statements concerning early clinical successes and whether they are predictive of the safety and efficacy of any medical device such as the CellFX nsPFA cardiac clamp, Pulse Biosciences’ expectations, whether stated or implied, regarding whether the Company’s CellFX nsPFA technology will become a disruptive treatment option for treating atrial fibrillation or any other medical condition, and other future events. These statements are not historical facts but rather are based on Pulse Biosciences’ current expectations, estimates, and projections regarding Pulse Biosciences’ business, operations and other similar or related factors. Words such as “may,” “will,” “could,” “would,” “should,” “anticipate,” “predict,” “potential,” “continue,” “expects,” “intends,” “plans,” “projects,” “believes,” “estimates,” and other similar or related expressions are used to identify these forward-looking statements, although not all forward-looking statements contain these words. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and assumptions that are difficult or impossible to predict and, in some cases, beyond Pulse Biosciences’ control. Actual results may differ materially from those in the forward-looking statements as a result of a number of factors, including those described in Pulse Biosciences’ filings with the Securities and Exchange Commission. Pulse Biosciences undertakes no obligation to revise or update information in this release to reflect events or circumstances in the future, even if new information becomes available.

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