FDA 510(k) Premarket Notification

K233705 CellFX Percutaneous Electrode System (SYS3000)

CLEARED

Mar 8, 2024
109 days to decision

K233705 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233705/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 20, 2023
Decision date	Mar 8, 2024
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pulse Biosciences, Inc.**
Location	Hayward, CA, US
Contact	Uyen Mai
510(k) history	7 submissions · 7 cleared · 2021-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k233705/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026