FDA 510(k) Premarket Notification

K240782 CellFX Percutaneous Electrode System (SYS3000)

CLEARED

Aug 5, 2024
137 days to decision

K240782 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k240782/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 21, 2024
Decision date	Aug 5, 2024
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CellFX Percutaneous Electrode, 13G (CPE013); CellFX Percutaneous Electrode, 18G (CPE018)

APPLICANT

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