FDA 510(k) Premarket Notification

K203299 CellFX System

CLEARED

Feb 2, 2021
85 days to decision

K203299 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k203299/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 9, 2020
Decision date	Feb 2, 2021
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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