FDA 510(k) Premarket Notification

CLEARED

K221672 Creo Electrosurgical System with NP1 Instrument

Feb 14, 2023
250 days to decision

K221672 · Product code: **NEY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221672/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Jun 9, 2022
Decision date	Feb 14, 2023
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Creo Medical, Ltd.**
Location	Chepstow, GB
Contact	Tiffany Powell
510(k) history	10 submissions · 9 cleared · 2017-2025

REGULATORY CONSULTANT

Consulting firm	**Phil Triolo and Associates LC**
Contact	Phil Triolo

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov