FDA 510(k) Premarket Notification

K200298 ABI Instrument, Creo Electrosurgical System

CLEARED

Jan 5, 2021
334 days to decision

K200298 · Product code: **NEY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200298/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Feb 6, 2020
Decision date	Jan 5, 2021
Days to decision	334 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Creo Medical, Ltd.**
Location	Chepstow, GB
Contact	Patrick Burn
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