FDA 510(k) Premarket Notification

# K223138 AB1 Electrosurgical Instrument, Creo Electrosurgical System

**CLEARED**

Jun 26, 2023
265 days to decision

K223138 · Product code: **NEY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223138/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Ablation, Microwave And Accessories (NEY) |
| Date received | Oct 4, 2022 |
| Decision date | Jun 26, 2023 |
| Days to decision | 265 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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