FDA 510(k) Premarket Notification

K211217 Profound Matrix

CLEARED

Dec 16, 2021
237 days to decision

K211217 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k211217/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 23, 2021
Decision date	Dec 16, 2021
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Candela Corporation**
Location	Wayland, MA, US
Contact	Jeffrey Churchill
510(k) history	8 submissions · 8 cleared · 2015-2024