FDA 510(k) Premarket Notification

K210693 PLEXR PLUS

CLEARED

Mar 22, 2022
379 days to decision

K210693 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k210693/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 8, 2021
Decision date	Mar 22, 2022
Days to decision	379 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Gmv S.R.L.**
Location	Rome, IT
Contact	Andrea Cancelli
510(k) history	1 submissions · 1 cleared · 2022-2022