FDA 510(k) Premarket Notification

K191542 Apyx Plasma/RF Handpiece

CLEARED

Oct 11, 2019
122 days to decision

K191542 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191542/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 11, 2019
Decision date	Oct 11, 2019
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bovie Medical Corporation Dba Apyx Medical Corporation**
Location	Clearwater, FL, US
Contact	Topaz Kirlew
510(k) history	2 submissions · 2 cleared · 2019-2019