FDA 510(k) Premarket Notification

CLEARED

K192867 Apyx Helium Plasma Generator (APYX-200H/P, APYX-JS3/RS3)

Oct 31, 2019
24 days to decision

K192867 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k192867/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 7, 2019
Decision date	Oct 31, 2019
Days to decision	24 days
Third-party review	Yes
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

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov