FDA 510(k) Premarket Notification

K202880 J-Plasma Precise FLEX Handpiece

CLEARED

Jan 4, 2021
98 days to decision

K202880 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k202880/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 28, 2020
Decision date	Jan 4, 2021
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Apyx Medical Corporation(Formerly Bovie Medical Corporation)**
Location	Clearwater, FL, US
Contact	Lauren Tiller
510(k) history	4 submissions · 4 cleared · 2019-2022