FDA 510(k) Premarket Notification

K230586 Renuvion® Micro Handpiece

CLEARED

Jun 9, 2023
99 days to decision

K230586 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k230586/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 2, 2023
Decision date	Jun 9, 2023
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Apyx Medical Corporation**
Location	Clearwater, FL, US
Contact	Mark D Evans
510(k) history	5 submissions · 5 cleared · 2022-2025