FDA 510(k) Premarket Notification

K223262 Renuvion® APR Handpiece

CLEARED

Feb 23, 2023
122 days to decision

K223262 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223262/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 24, 2022
Decision date	Feb 23, 2023
Days to decision	122 days
Third-party review	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