FDA 510(k) Premarket Notification

K220970 Renuvion APR Handpiece

CLEARED

Jul 15, 2022
102 days to decision

K220970 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220970/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 4, 2022
Decision date	Jul 15, 2022
Days to decision	102 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	Priscilla Herpai
510(k) history	4 submissions · 4 cleared · 2019-2022

CLINICAL EVIDENCE - NCT04146467

Renuvion APR Device to Improve the Appearance of Lax Tissue in the Neck and Submental Region

Status	Completed
Enrollment	82 patients (actual)
Study sites	6 sites
Condition studied	Lax Skin
Primary purpose	Treatment
Study type	Interventional
Study design	Sequential
Masking	Open label
Completion date	Feb 28, 2022
Sponsor	Apyx Medical (Industry)

Primary outcome

Day 180 Number of Participants With Improvement Measured By Independent Photographic Review

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04146467