

K211652 Renuvion Dermal Handpiece, Renuvion Dermal System

May 25, 2022
362 days to decisionK211652 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k211652/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	May 28, 2021
Decision date	May 25, 2022
Days to decision	362 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	Topaz Kirlew
510(k) history	4 submissions · 4 cleared · 2019-2022

CLINICAL EVIDENCE - NCT03286283

The Use of J-Plasma® for Dermal Resurfacing

Status	Completed
Enrollment	55 patients (actual)
Study sites	3 sites
Condition studied	Facial Wrinkles; Rhytides
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Nov 16, 2018
Sponsor	Apyx Medical (Industry)

Primary outcome

Improvement in Fitzpatrick Wrinkle and Elastosis Scale (FWS) Score

Secondary outcome

Number of Participants With a ? 1-score Improvement on the Fitzpatrick Wrinkle and Elastosis Scale (FWS) and at Least an "Improved" Rating on the Modified Global Aesthetic Improvement Scale (GAIS) at the 3-month Visit.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03286283