FDA 510(k) Premarket Notification

K201738 SubNovii Advanced Plasma Technology

CLEARED

Sep 10, 2020
77 days to decision

K201738 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k201738/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 25, 2020
Decision date	Sep 10, 2020
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cartessa Aesthetics**
Location	Melville, NY, US
Contact	Gabe Lubin
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Hoy and Associates**
Contact	Connie Hoy

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov