FDA 510(k) Premarket Notification

K212678 Viveve System, Viveve 2.0 System

CLEARED

Sep 14, 2021
21 days to decision

K212678 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212678/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 24, 2021
Decision date	Sep 14, 2021
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Viveve Medical, Inc.**
Location	Englewood, CO, US
Contact	Kevin Robison
510(k) history	3 submissions · 3 cleared · 2020-2021