FDA 510(k) Premarket Notification

CLEARED

K160754 Venclose Radiofrequency System (digiRF Generator, EVSRF Catheter)

Sep 9, 2016
175 days to decision

K160754 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k160754/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 18, 2016
Decision date	Sep 9, 2016
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Venclose, Inc.**
Location	San Jose, CA, US
Contact	MAI LY WILCOX
510(k) history	4 submissions · 4 cleared · 2016-2025