FDA 510(k) Premarket Notification

K200169 VFS1 Bipolar Electrosurgical Generator

CLEARED

May 14, 2020
112 days to decision

K200169 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200169/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jan 23, 2020
Decision date	May 14, 2020
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**FHC, Inc.**
Location	Bowdoinham, ME, US
Contact	Kelly Moeykens
510(k) history	12 submissions · 12 cleared · 2000-2023