FDA 510(k) Premarket Notification

K102983 VASCUCLEAR PRECISION BIPOLAR

CLEARED

Nov 1, 2010
25 days to decision

K102983 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k102983/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 7, 2010
Decision date	Nov 1, 2010
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sorin Group USA, Inc.**
Location	Arvada, CO, US
Contact	SCOTT LIGHT
510(k) history	2 submissions · 2 cleared · 2010-2013