FDA 510(k) Premarket Notification

K131758 SURGEN U

CLEARED

Dec 18, 2013
184 days to decision

K131758 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k131758/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 17, 2013
Decision date	Dec 18, 2013
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pollogen, Ltd.**
Location	Binyamina, IL
Contact	JONATHAN S KAHAN
510(k) history	18 submissions · 18 cleared · 2011-2025