FDA 510(k) Premarket Notification

K130983 GENII ARC SMART ARGON PROBE

CLEARED

Sep 26, 2013
170 days to decision

K130983 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k130983/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 9, 2013
Decision date	Sep 26, 2013
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Genii, Inc.**
Location	Austin, TX, US
Contact	TRACY EBERLY
510(k) history	2 submissions · 2 cleared · 2012-2013