FDA 510(k) Premarket Notification

K162053 PhotonBlade

CLEARED

Sep 15, 2016
52 days to decision

K162053 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k162053/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jul 25, 2016
Decision date	Sep 15, 2016
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Invuity, Inc.**
Location	Sunnyvale, CA, US
Contact	John Kang
510(k) history	4 submissions · 4 cleared · 2009-2020