FDA 510(k) Premarket Notification

K150915 SPINAUT-P

CLEARED

Mar 18, 2016
347 days to decision

K150915 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k150915/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 6, 2015
Decision date	Mar 18, 2016
Days to decision	347 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Imedicom Co., Ltd.**
Location	Gunpo-Si, KR
Contact	BONGGU HA
510(k) history	6 submissions · 6 cleared · 2016-2019