FDA 510(k) Premarket Notification

K101111 HALO ABLATION CATHETER MODEL 90-9100, HALO90 ULTRA ABLATION CATHETER MODEL 90-9200

CLEARED

Jun 18, 2010
58 days to decision

K101111 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k101111/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 21, 2010
Decision date	Jun 18, 2010
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Barrx Medical, Inc.**
Location	Sunnyvale, CA, US
Contact	VIORICA FILIMON
510(k) history	3 submissions · 3 cleared · 2010-2012