FDA 510(k) Premarket Notification

K163105 Emprint Ablation System

CLEARED

Dec 6, 2016
29 days to decision

K163105 · Product code: **NEY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k163105/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Nov 7, 2016
Decision date	Dec 6, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Covidien, LLC**
Location	Mansfield, MA, US
Contact	PATTI ARNDT
510(k) history	88 submissions · 85 cleared · 2010-2026