FDA 510(k) Premarket Notification

K133821 EMPRINT ABLATION SYSTEM

CLEARED

Apr 28, 2014
133 days to decision

K133821 · Product code: **NEY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k133821/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Dec 16, 2013
Decision date	Apr 28, 2014
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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