FDA 510(k) Premarket Notification

K150313 Ablation Confirmation

CLEARED

Jul 9, 2015
150 days to decision

K150313 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k150313/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 9, 2015
Decision date	Jul 9, 2015
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neuwave Medical, Inc.**
Location	Madision, WI, US
Contact	DAN KOSEDNAR
510(k) history	15 submissions · 15 cleared · 2010-2024