

K160936 Certus 140 2.45GHz Ablation SystemMay 4, 2016
30 days to decisionK160936 · Product code: **NEY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k160936/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Apr 4, 2016
Decision date	May 4, 2016
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160936/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026