

**K161285 Ablation Confirmation**Jun 29, 2016  
51 days to decisionK161285 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k161285/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	May 9, 2016
Decision date	Jun 29, 2016
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161285/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026