

K192427 Ablation ConfirmationOct 3, 2019
28 days to decisionK192427 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k192427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Sep 5, 2019
Decision date	Oct 3, 2019
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192427/> 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