

**K232227 ABLATE-IQ**Apr 4, 2024  
252 days to decisionK232227 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k232227/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jul 27, 2023
Decision date	Apr 4, 2024
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232227/> 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 14, 2026