

K160126 AIRO Computed Tomography (CT) X-ray SystemApr 19, 2016
90 days to decisionK160126 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k160126/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jan 20, 2016
Decision date	Apr 19, 2016
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mobius Imaging
Location	Shirley, MA, US
Contact	Norma J LeMay
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160126/> 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 16, 2026