

K180393 AIRO Computed Tomography (CT) X-ray SystemMar 15, 2018
30 days to decisionK180393 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k180393/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Feb 13, 2018
Decision date	Mar 15, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mobius Imaging, LLC
Location	Ayer, MA, US
Contact	Norma LeMay
510(k) history	2 submissions · 2 cleared · 2013-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180393/> 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