

**K162314 IMACTIS CT-Navigation system**Apr 24, 2018  
614 days to decisionK162314 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k162314/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Aug 18, 2016
Decision date	Apr 24, 2018
Days to decision	614 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Imactis, Sas</b>
Location	La Tronche, FR
Contact	MADY BATAILH
510(k) history	1 submissions · 1 cleared · 2018-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162314/> 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 16, 2026