

K192590 CURA 778Mar 5, 2020
167 days to decisionK192590 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k192590/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Sep 20, 2019
Decision date	Mar 5, 2020
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fmi Medical Systems, Inc.
Location	Solon, OH, US
Contact	Dazhuang Meng
510(k) history	2 submissions · 2 cleared · 2018-2020

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