

K191394 ILLUMISITE PlatformAug 7, 2019
75 days to decisionK191394 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k191394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	May 24, 2019
Decision date	Aug 7, 2019
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Kristi Fox
510(k) history	88 submissions · 85 cleared · 2010-2026

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