

**K010813 SIMPLICT**May 7, 2001  
49 days to decisionK010813 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k010813/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Mar 19, 2001
Decision date	May 7, 2001
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neorad AS</b>
Location	Chapel Hill, NC, US
Contact	CHARLES H KYPER
510(k) history	1 submissions · 1 cleared · 2001-2001

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