

**K082830 INFX-8000H, INFINIX-I**Oct 10, 2008  
14 days to decisionK082830 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k082830/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Sep 26, 2008
Decision date	Oct 10, 2008
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Toshiba America Medical Systems, In.C</b>
Location	Tustin, CA, US
510(k) history	146 submissions · 146 cleared · 1989-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082830/>, 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