

K081621 INFX-8000C (INFINIX CC-I AND VC-I)Jun 23, 2008
14 days to decisionK081621 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k081621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Jun 9, 2008
Decision date	Jun 23, 2008
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Toshiba America Medical Systems, In.C
Location	Tustin, CA, US
Contact	PAUL BIGGINS
510(k) history	146 submissions · 146 cleared · 1989-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081621/> Data sourced from FDA 510(k) public records (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. - Generated May 16, 2026