

**K152696 INFX-8000V, V6.20**Jan 12, 2016  
113 days to decisionK152696 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k152696/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 21, 2015
Decision date	Jan 12, 2016
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Toshibamedical Systems Corporation</b>
Location	Tustin, CA, US
Contact	Paul Biggins
510(k) history	80 submissions · 80 cleared · 2004-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152696/> 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