

K162614 Infinix, INFX-8000V, V6.35Oct 17, 2016
28 days to decisionK162614 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k162614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 19, 2016
Decision date	Oct 17, 2016
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Toshibamedical Systems Corporation
Location	Tustin, CA, US
Contact	PAUL BIGGINS
510(k) history	80 submissions · 80 cleared · 2004-2018

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