

K152697 INFX-8000C, V6.20Jan 15, 2016
116 days to decisionK152697 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k152697/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 21, 2015
Decision date	Jan 15, 2016
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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