

K103425 ZEN-7000, FLUOROSCOPIC X-RAY SYSTEMMar 29, 2011
127 days to decisionK103425 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k103425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Nov 22, 2010
Decision date	Mar 29, 2011
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genoray America, Inc.
Location	Orange, CA, US
Contact	JAE KIM
510(k) history	1 submissions · 1 cleared · 2011-2011

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