

K013608 DIGITAL RADIOGRAPHY SYSTEM, MODEL DFP-8000DNov 15, 2001
15 days to decisionK013608 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k013608/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Oct 31, 2001
Decision date	Nov 15, 2001
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013608/> 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