FDA 510(k) Premarket Notification

# K013608 DIGITAL RADIOGRAPHY SYSTEM, MODEL DFP-8000D

**CLEARED**

Nov 15, 2001
15 days to decision

K013608 · 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 |