FDA 510(k) Premarket Notification

K082830 INFX-8000H, INFINIX-I

CLEARED

Oct 10, 2008
14 days to decision

K082830 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k082830/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Sep 26, 2008
Decision date	Oct 10, 2008
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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