FDA 510(k) Premarket Notification

K172646 XIDF-AWS801, Angio Workstation, V7.0

CLEARED

Oct 30, 2017
59 days to decision

K172646 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k172646/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 1, 2017
Decision date	Oct 30, 2017
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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