FDA 510(k) Premarket Notification

K181407 Artis zee/zeego & Artis Q/Q.zen

CLEARED

Aug 15, 2018
77 days to decision

K181407 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k181407/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	May 30, 2018
Decision date	Aug 15, 2018
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medical Solution USA, Inc.**
Location	Malvern, PA, US
Contact	Patricia D. Jones
510(k) history	8 submissions · 8 cleared · 2017-2022