FDA 510(k) Premarket Notification

K152218 AVERT Contrast Modulation System

CLEARED

Sep 21, 2015
45 days to decision

K152218 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k152218/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Aug 7, 2015
Decision date	Sep 21, 2015
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary
Other names	AVERT Contrast Modulation System;AVERT Contrast Modulation System

APPLICANT

Company	**Osprey Medical**
Location	Minnetonka, MN, US
Contact	Melanie Hess
510(k) history	1 submissions · 1 cleared · 2015-2015