FDA 510(k) Premarket Notification

K121303 MOBILE C-ARM

CLEARED

Jul 26, 2012
86 days to decision

K121303 · Product code: **OXO** · Radiology
Source: https://www.510kdatabase.net/k121303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image-intensified Fluoroscopic X-ray System, Mobile (OXO)
Date received	May 1, 2012
Decision date	Jul 26, 2012
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Canon Inc. -Medical Equipment Group**
Location	Tachikawa-Shi, Tokyo, JP
Contact	DIANE RUTHERFORD
510(k) history	11 submissions · 11 cleared · 2010-2018