FDA 510(k) Premarket Notification

K140683 0180 INTUITION, 0072 PRECISION

CLEARED

Jun 3, 2014
77 days to decision

K140683 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k140683/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	Mar 18, 2014
Decision date	Jun 3, 2014
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Arcoma AB**
Location	Vaxjo, SE
Contact	DANIEL KAMM
510(k) history	2 submissions · 2 cleared · 2008-2014