FDA 510(k) Premarket Notification

K163210 Philips CombiDiagnost R90

CLEARED

Jan 31, 2017
77 days to decision

K163210 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k163210/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Nov 15, 2016
Decision date	Jan 31, 2017
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems Dmc GmbH**
Location	Seneca, SC, US
Contact	Ming Xiao
510(k) history	18 submissions · 18 cleared · 2013-2024