FDA 510(k) Premarket Notification

K163410 DigitalDiagnost C50

CLEARED

Jan 4, 2017
30 days to decision

K163410 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k163410/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	Dec 5, 2016
Decision date	Jan 4, 2017
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Healthcare (Suzhou) Co., Ltd.**
Location	Suzhou Jiangsu, CN
Contact	ALINA ZHOU
510(k) history	17 submissions · 17 cleared · 2014-2026