FDA 510(k) Premarket Notification

K190601 MasteRad MX30

CLEARED

Apr 25, 2019
48 days to decision

K190601 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k190601/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Mar 8, 2019
Decision date	Apr 25, 2019
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medicatech USA**
Location	Deer Field, IL, US
Contact	George Makar
510(k) history	9 submissions · 9 cleared · 2008-2023