FDA 510(k) Premarket Notification

K181989 MRIdian Linac System

CLEARED

Feb 20, 2019
209 days to decision

K181989 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k181989/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 26, 2018
Decision date	Feb 20, 2019
Days to decision	209 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Viewray, Incorporated**
Location	Oakwood Village, OH, US
Contact	Sean Delaney
510(k) history	6 submissions · 6 cleared · 2011-2021