FDA 510(k) Premarket Notification

K221853 OTC DDR

CLEARED

Jul 27, 2022
30 days to decision

K221853 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k221853/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	Jun 27, 2022
Decision date	Jul 27, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Konica Minolta Healthcare Americas, Inc.**
Location	Garner, NC, US
Contact	Jan Maniscalco
510(k) history	5 submissions · 5 cleared · 2020-2022