FDA 510(k) Premarket Notification

K192364 GXR-Series Diagnostic X-Ray System

CLEARED

Sep 26, 2019
27 days to decision

K192364 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k192364/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Aug 30, 2019
Decision date	Sep 26, 2019
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**DRGEM Corporation**
Location	Echo, OR, US
Contact	Ki-Nam Yang
510(k) history	13 submissions · 13 cleared · 2010-2025