FDA 510(k) Premarket Notification

CLEARED

K182134 ARiX RAD Radiographic System

Nov 26, 2018
112 days to decision

K182134 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k182134/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Aug 6, 2018
Decision date	Nov 26, 2018
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Compania Mexicana DE Radiologia Cgr, S.A. DE C.V.**
Location	Denton, TX, US
Contact	Tonatiuh Monroy Soberon
510(k) history	4 submissions · 4 cleared · 2013-2020

REGULATORY CONSULTANT

Consulting firm	**Emergo Global Consulting, LLC**
Contact	Stuart R. Goldman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov