FDA 510(k) Premarket Notification

K213700 MULTIX Impact, MULTIX Impact C

CLEARED

Dec 13, 2021
20 days to decision

K213700 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k213700/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	Nov 23, 2021
Decision date	Dec 13, 2021
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medical Solutions USA, Inc.**
Location	Hoffman Estates, IL, US
Contact	Denise Adams
510(k) history	778 submissions · 778 cleared · 1980-2026