FDA 510(k) Premarket Notification

K230955 syngo Application Software

CLEARED

Dec 20, 2023
260 days to decision

K230955 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k230955/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 4, 2023
Decision date	Dec 20, 2023
Days to decision	260 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	Patricia D Jones
510(k) history	778 submissions · 778 cleared · 1980-2026