FDA 510(k) Premarket Notification

K232000 syngo.via MI Workflows

CLEARED

Nov 28, 2023
146 days to decision

K232000 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k232000/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 5, 2023
Decision date	Nov 28, 2023
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Scenium; syngo MBF

APPLICANT

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