FDA 510(k) Premarket Notification

K230196 syngo.via View&GO VA40A

CLEARED

Feb 13, 2023
19 days to decision

K230196 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k230196/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 25, 2023
Decision date	Feb 13, 2023
Days to decision	19 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Healthcare GmbH**
Location	Erlangen, DE
Contact	Frederike Jakob
510(k) history	30 submissions · 30 cleared · 2016-2026

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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