FDA 510(k) Premarket Notification

K230561 Syngo Carbon Space VA30A

CLEARED

Mar 21, 2023
21 days to decision

K230561 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k230561/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 28, 2023
Decision date	Mar 21, 2023
Days to decision	21 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Healthcare GmbH**
Location	Erlangen, DE
Contact	Vijay Ramadas
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