FDA 510(k) Premarket Notification

K182208 syngo.via View&GO (Version VA10A)

CLEARED

Sep 7, 2018
23 days to decision

K182208 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k182208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 15, 2018
Decision date	Sep 7, 2018
Days to decision	23 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Tuv Sud America, Inc.**
Contact	Alexander Schapovalov

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