FDA 510(k) Premarket Notification

K210054 Cios Spin

CLEARED

Feb 5, 2021
28 days to decision

K210054 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k210054/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jan 8, 2021
Decision date	Feb 5, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medical Systems USA, Inc.**
Location	Malvern, PA, US
Contact	Cordell Fields
510(k) history	2 submissions · 2 cleared · 2018-2021

REGULATORY CONSULTANT

Consulting firm	**Siemens Healthcare GmbH**
Contact	Cordell Fields

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