FDA 510(k) Premarket Notification

K232206 SOMATOM Pro.Pulse

CLEARED

Dec 6, 2023
134 days to decision

K232206 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k232206/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jul 25, 2023
Decision date	Dec 6, 2023
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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