

K190578 SOMATOM Force, SOMATOM Definition Flash, SOMATOM Drive, SOMATOM Definition Edge, SOMATOM Definition AS Open, SOMATOM Edge Plus, SOMATOM Definition AS/AS+, SOMATOM ConfidenceJun 27, 2019
113 days to decisionK190578 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k190578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Mar 6, 2019
Decision date	Jun 27, 2019
Days to decision	113 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	Kimberly Mangum
510(k) history	779 submissions · 779 cleared · 1980-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190578/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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