

K203720 MICROMATEJun 22, 2021
183 days to decisionK203720 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k203720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Dec 21, 2020
Decision date	Jun 22, 2021
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Isys Medizintechnik GmbH
Location	Stamford, CT, US
Contact	Michael Vogele
510(k) history	3 submissions · 3 cleared · 2014-2023

REGULATORY CONSULTANT

Consulting firm	Cdi Regulatory Consultants
Contact	Cornelia Damsky

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

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