

K200965 XR-MX/1000Dec 29, 2020
263 days to decisionK200965 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k200965/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Apr 10, 2020
Decision date	Dec 29, 2020
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	KARL STORZ Endoscopy-America, Inc.
Location	Mchenry, IL, US
Contact	Winkie Wong
510(k) history	361 submissions · 361 cleared · 1980-2024

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