

K212890 Nyquist.IQDec 13, 2021
94 days to decisionK212890 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k212890/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Sep 10, 2021
Decision date	Dec 13, 2021
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Omega Medical Imaging, LLC
Location	Sanford, FL, US
Contact	John Newman
510(k) history	7 submissions · 7 cleared · 2012-2025

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