

K192761 Asimov-MKS Imaging SystemJan 17, 2020
109 days to decisionK192761 · Product code: **IZI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192761/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Sep 30, 2019
Decision date	Jan 17, 2020
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Onlume, Inc.
Location	Madison, WI, US
Contact	Greg Bange
510(k) history	1 submissions · 1 cleared · 2020-2020

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