

K212654 Micro C Medical Imaging System, M01Feb 4, 2022
165 days to decisionK212654 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k212654/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Aug 23, 2021
Decision date	Feb 4, 2022
Days to decision	165 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oxos Medical, Inc.
Location	Atlanta, GA, US
Contact	Evan Ruff
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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