

**K203658 Micro C Medical Imaging System, M01**Jan 12, 2021  
28 days to decisionK203658 · Product code: **IZL** · Radiology  
Source: <https://www.510kdatabase.net/k203658/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Dec 15, 2020
Decision date	Jan 12, 2021
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
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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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203658/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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