

**K230918 MasterX 800 Series**Sep 1, 2023  
151 days to decisionK230918 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k230918/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Apr 3, 2023
Decision date	Sep 1, 2023
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicatech USA</b>
Location	Deer Field, IL, US
Contact	George Makar
510(k) history	9 submissions · 9 cleared · 2008-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Kamm &amp; Associates</b>
Contact	Daniel Kamm

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/k230918/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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