

**K232552 TuxDeluxe (Size 1 6100B, Size 2 6101B)**Oct 20, 2023  
58 days to decisionK232552 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k232552/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Aug 23, 2023
Decision date	Oct 20, 2023
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tuxedo Imaging, LLC</b>
Location	Akron, OH, US
Contact	Patrick Williams
510(k) history	1 submissions · 1 cleared · 2023-2023

**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](https://accessdata.fda.gov)

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