

K203116 SensorXMar 19, 2021
154 days to decisionK203116 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k203116/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Oct 16, 2020
Decision date	Mar 19, 2021
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Durr Dental SE
Location	Bietigheim-Bissingen, DE
Contact	Oliver Lange
510(k) history	9 submissions · 9 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	Kamm & Associates
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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