

K230095 ScanX Swift 2.0, ScanX Swift View 2.0Feb 6, 2023
25 days to decisionK230095 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k230095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jan 12, 2023
Decision date	Feb 6, 2023
Days to decision	25 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

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