

K260082 TRIOS Dx (R1)Apr 10, 2026
88 days to decisionK260082 · Product code: **SHQ** · Dental
Source: <https://www.510kdatabase.net/k260082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Jan 12, 2026
Decision date	Apr 10, 2026
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3Shape TRIOS A/S
Location	Copenhagen, DK
Contact	Jenny Axel
510(k) history	3 submissions · 3 cleared · 2022-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260082/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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