

**K242103 TRIOS Ready Tip**Apr 4, 2025  
260 days to decisionK242103 · Product code: **NBL** · Dental  
Source: <https://www.510kdatabase.net/k242103/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Fluorescence Caries Detection (NBL)
Date received	Jul 18, 2024
Decision date	Apr 4, 2025
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3Shape TRIOS A/S</b>
Location	Copenhagen, DK
Contact	Klaus Rudbaek Hoj
510(k) history	3 submissions · 3 cleared · 2022-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242103/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026