

K221249 L1P-1F (TRIOS 5)Sep 16, 2022
137 days to decisionK221249 · Product code: **NBL** · Dental
Source: <https://www.510kdatabase.net/k221249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Fluorescence Caries Detection (NBL)
Date received	May 2, 2022
Decision date	Sep 16, 2022
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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