

K261847 iTero Lumina™ Pro

Jul 2, 2026
29 days to decision

K261847 · Product code: NTK · Dental
Source: <https://www.510kdatabase.net/k261847/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Caries Detector, Laser Light, Transmission (NTK)
Date received	Jun 3, 2026
Decision date	Jul 2, 2026
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Align Technology , Ltd.
Location	Petach Tikva, IL
Contact	Aviva Touati
510(k) history	2 submissions · 2 cleared · 2024-2026