

K221275 Qraycam PROSep 4, 2024
856 days to decisionK221275 · Product code: **NBL** · Dental
Source: <https://www.510kdatabase.net/k221275/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Fluorescence Caries Detection (NBL)
Date received	May 2, 2022
Decision date	Sep 4, 2024
Days to decision	856 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	AIOBIO Co., Ltd.
Location	Seongnam-Si, KR
Contact	HongCheol Yoon
510(k) history	2 submissions · 2 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	KMC, Inc.
Contact	JeongKeun Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov
