

K222560 BlueCheck™ Caries Detection & MonitoringMay 16, 2023
265 days to decision

K222560 · Product code: LFC · Dental

Source: <https://www.510kdatabase.net/k222560/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Caries Detection (LFC)
Date received	Aug 24, 2022
Decision date	May 16, 2023
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Incisive Technologies Pty, Ltd.
Location	Melbourne, AU
Contact	Kerry A Hegarty
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Melissa Burbage

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

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