

K213795 Videa Caries AssistApr 21, 2022
136 days to decisionK213795 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k213795/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Dec 6, 2021
Decision date	Apr 21, 2022
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Videahealth, Inc.
Location	Boston, MA, US
Contact	Florian Hillen
510(k) history	4 submissions · 4 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting
Contact	Donna-Bea Tillman

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

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