

K203500 RetCam EnvisionApr 13, 2021
134 days to decisionK203500 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k203500/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Nov 30, 2020
Decision date	Apr 13, 2021
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Natus Medical Incorporated Dba Excel-Tech Ltd. (Xitek)
Location	Oakville, CA
Contact	Sanjay Mehta
510(k) history	13 submissions · 13 cleared · 2016-2024

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