FDA 510(k) Premarket Notification

CLEARED

K221872 ITrack Advance Canaloplasty Microcatheter with Advanced Delivery System

Mar 30, 2023
275 days to decision

K221872 · Product code: **MPA** · Ophthalmic
Source: https://www.510kdatabase.net/k221872/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Endoilluminator (MPA)
Date received	Jun 28, 2022
Decision date	Mar 30, 2023
Days to decision	275 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nova Eye Inc. (Business Name Nova Eye Medical)**
Location	Fremont, CA, US
Contact	Don Watton
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Eds Regulatory Consulting, Inc.**
Contact	Evelyn De La Vega Stewart

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