FDA 510(k) Premarket Notification

CLEARED

K202670 Nam illumination probe with chopper

Aug 20, 2021
340 days to decision

K202670 · Product code: **MPA** · Ophthalmic
Source: https://www.510kdatabase.net/k202670/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoilluminator (MPA)
Date received	Sep 14, 2020
Decision date	Aug 20, 2021
Days to decision	340 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Oculight , Ltd.**
Location	Seongnam-Si, KR
Contact	Jinman Kim
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Medical Device Academy, Inc.**
Contact	Robert Packard

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