FDA 510(k) Premarket Notification

K191846 MAXReach Laser Probe

CLEARED

Dec 23, 2019
166 days to decision

K191846 · Product code: **HQB** · Ophthalmic
Source: https://www.510kdatabase.net/k191846/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Photocoagulator And Accessories (HQB)
Date received	Jul 10, 2019
Decision date	Dec 23, 2019
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vortex Surgical, Inc.**
Location	Chesterfield, MO, US
Contact	Bob Neu
510(k) history	2 submissions · 2 cleared · 2019-2022