FDA 510(k) Premarket Notification

K182646 Vitreq disposable laser probes, light fibers and Chandelier

CLEARED

May 1, 2019
219 days to decision

K182646 · Product code: **HQB** · Ophthalmic
Source: https://www.510kdatabase.net/k182646/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Photocoagulator And Accessories (HQB)
Date received	Sep 24, 2018
Decision date	May 1, 2019
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vitreq BV**
Location	Vierpolders, NL
Contact	JanKees Wouts
510(k) history	2 submissions · 2 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	**Beaver-Visitec International, Inc.**
Contact	Genci Omari

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