FDA 510(k) Premarket Notification

K202038 CryoTreQ

CLEARED

Dec 30, 2020
160 days to decision

K202038 · Product code: **HPS** · Ophthalmic
Source: https://www.510kdatabase.net/k202038/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryophthalmic (HPS)
Date received	Jul 23, 2020
Decision date	Dec 30, 2020
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Dynamic Strategies, Inc.**
Contact	Debora Stapleton

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