

K202038 CryoTreQDec 30, 2020
160 days to decisionK202038 · 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	Vitrex BV
Location	Vierpolders, NL
Contact	Christian Neele
510(k) history	2 submissions · 2 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	Dynamic Strategies, Inc.
Contact	Debra Stapleton

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202038/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 14, 2026