

K193556 Cryocheck Hex LAOct 23, 2020
305 days to decisionK193556 · Product code: **GFO** · Hematology
Source: <https://www.510kdatabase.net/k193556/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Partial Thromboplastin (GFO)
Date received	Dec 23, 2019
Decision date	Oct 23, 2020
Days to decision	305 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Precision Biologic
Location	Dartmouth, N.S., CA
Contact	Karen Black
510(k) history	10 submissions · 10 cleared · 1999-2020

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