

K231804 PRIME-XV Freezis DMSO-Free MDNov 9, 2023
142 days to decisionK231804 · Product code: **NDS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k231804/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Media, Culture, Ex Vivo, Tissue And Cell (NDS)
Date received	Jun 20, 2023
Decision date	Nov 9, 2023
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Irvine Scientific
Location	Santa Ana, CA, US
Contact	Amanda Cinquin
510(k) history	4 submissions · 4 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231804/> 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 May 25, 2026