

K220981 SUPERPLAST Double-Occluder, SUPERPLAST Vascular ProbeApr 20, 2023
381 days to decisionK220981 · Product code: **DWP** · Cardiovascular
Source: <https://www.510kdatabase.net/k220981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, Surgical (DWP)
Date received	Apr 4, 2022
Decision date	Apr 20, 2023
Days to decision	381 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fehling Surgical Instruments, Inc.
Location	Kennesaw, GA, US
Contact	Hayden Hosch
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Jalex Medical
Contact	Jennifer Palinchik

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/k220981/> 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 26, 2026