FDA 510(k) Premarket Notification

CLEARED

K220981 SUPERPLAST Double-Occluder, SUPERPLAST Vascular Probe

Apr 20, 2023
381 days to decision

K220981 · 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