FDA 510(k) Premarket Notification

K200289 Michler-Kapp Cardiovascular Vent Catheter

CLEARED

Jan 28, 2021
358 days to decision

K200289 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k200289/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Feb 5, 2020
Decision date	Jan 28, 2021
Days to decision	358 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kapp Surgical Instrument, Inc.**
Location	Mchenry, IL, US
Contact	Nicole Merrifield
510(k) history	9 submissions · 9 cleared · 1984-2021

REGULATORY CONSULTANT

Consulting firm	**Cro Group, Inc.**
Contact	William McLain

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