FDA 510(k) Premarket Notification

K221914 Catapult Guide Sheath

CLEARED

Jul 29, 2022
29 days to decision

K221914 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k221914/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jun 30, 2022
Decision date	Jul 29, 2022
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Contract Medical International, GmbH**
Location	Dresden, DE
Contact	Juliana Vaz Nuernberger
510(k) history	7 submissions · 7 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	**Contract Medical International S.R.O.**
Contact	Jan Kubicek

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