FDA 510(k) Premarket Notification

K220604 EXTesia Introducer Sheath Set

CLEARED

Apr 27, 2022
56 days to decision

K220604 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k220604/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 2, 2022
Decision date	Apr 27, 2022
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Curatia Medical Co.**
Location	Santa Clara, CA, US
Contact	Jessica Chiu
510(k) history	2 submissions · 2 cleared · 2018-2022

REGULATORY CONSULTANT

Consulting firm	**Prime Path Medtech**
Contact	Breanne Butler

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