FDA 510(k) Premarket Notification

CLEARED

K202226 Lim Precision Steerable TS, Steerable Sheath, Dilator

Dec 15, 2020
130 days to decision

K202226 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k202226/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 7, 2020
Decision date	Dec 15, 2020
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Keystone Heart, Ltd.**
Location	Caesaria, IL
Contact	Jaime Sarabia
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Winegar Consulting, Inc.**
Contact	Mike Winegar

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