

**K202226 Lim Precision Steerable TS, Steerable Sheath, Dilator**Dec 15, 2020  
130 days to decisionK202226 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k202226/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Winegar Consulting, Inc.</b>
Contact	Mike Winegar

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202226/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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