CLEARED

Feb 10, 2022
283 days to decision

K211327 Khelix Steerable Electrophysiology Catheters, Khelix Loop Fixed Electrophysiology Catheters, Khelix Fixed Loop Steerable Electrophysiology Catheters, Khelix Variable Loop Steerable Electrophysiology Catheters

K211327 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k211327/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	May 3, 2021
Decision date	Feb 10, 2022
Days to decision	283 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**CathRx, Ltd.**
Location	Rydalmere, AU
Contact	Lucy Huang
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Acom N Oakes, LLC**
Contact	Amy Oakes

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