

K240004 CardioCurve Steerable Sheath Small Curl, 40cm (CC-1040S)Jan 31, 2024
29 days to decisionK240004 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k240004/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jan 2, 2024
Decision date	Jan 31, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CardioCurve Steerable Sheath Medium Curl, 40cm (CC-1040M); CardioCurve Steerable Sheath Large Curl, 40cm (CC-1040L); CardioCurve Steerable Sheath Small Curl, 61cm (CC-1061S); CardioCurve Steerable Sheath Medium Curl, 61cm (CC-1061M); CardioCurve Steerable Sheath Large Curl, 61cm (CC-1061L); CardioCurve Steerable Sheath Small Curl, 71cm (CC-1071S); CardioCurve Steerable Sheath Medium Curl, 71cm (CC-1071M); CardioCurve Steer

APPLICANT

Company	Circa Scientific, Inc.
Location	Englewood, CO, US
Contact	Alice Ouyang
510(k) history	6 submissions · 6 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240004/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026