

**K222538 NC ROCKSTAR Non-Compliant PTCA Balloon
Dilatation Catheter**Dec 21, 2022
121 days to decisionK222538 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k222538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Aug 22, 2022
Decision date	Dec 21, 2022
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sino Medical Sciences Technology, Inc.
Location	Tianjin, CN
Contact	Jianhua Sun
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	CardioMed Device Consultants, LLC
Contact	Semih Oktay

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222538/> 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 26, 2026