FDA 510(k) Premarket Notification

CLEARED

K223022 SC HONKYTONK PTCA Balloon Dilatation Catheter

Feb 15, 2023
139 days to decision

K223022 · Product code: **LOX** · Cardiovascular
Source: https://www.510kdatabase.net/k223022/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Sep 29, 2022
Decision date	Feb 15, 2023
Days to decision	139 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k223022/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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