

K202578 KardiFlex NC Coronary Dilatation CatheterMay 6, 2021
240 days to decisionK202578 · Product code: **LOX** · CardiovascularSource: <https://www.510kdatabase.net/k202578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Sep 8, 2020
Decision date	May 6, 2021
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medcaptain Life Science Co., Ltd.
Location	Shenzhen, CN
Contact	David Xia
510(k) history	5 submissions · 5 cleared · 2021-2023

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