

**K202619 KardiFlex PTCA Balloon Dilatation Catheter**Apr 29, 2021  
231 days to decisionK202619 · Product code: **LOX** · CardiovascularSource: <https://www.510kdatabase.net/k202619/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Sep 10, 2020
Decision date	Apr 29, 2021
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202619/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026