

**K212393 OPN NC PTCA Dilatation Catheter**Mar 14, 2022  
224 days to decisionK212393 · Product code: **LOX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k212393/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Aug 2, 2021
Decision date	Mar 14, 2022
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sis Medical AG</b>
Location	Frauenfeld, CH
Contact	Sergej Kammerzell
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Cardiomed Device Consultants</b>
Contact	H. Semih Oktay

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212393/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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