

**K193495 XO Score Percutaneous Transluminal Angioplasty  
Scoring Catheter**May 29, 2020  
164 days to decisionK193495 · Product code: **PNO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k193495/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Dec 17, 2019
Decision date	May 29, 2020
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Transit Scientific</b>
Location	Salt Lake City, UT, US
Contact	Jennifer Arnold
510(k) history	2 submissions · 2 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>University of Utah</b>
Contact	Srividya Pothana

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193495/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026