K231821 XO Cath Microcatheter (E20-090-S, E20-110-S, E20-130-S, E20-150-S, E20-175-S, E20-220-S, E20-090-B, E20-110-B, E20-130-B, E20-150-B, E20-175-B, E20-220-B, E26-090-S, E26-110-S, E26-130-S, E26-150-S, E26-175-S, E26-220-S, E26-090-B, E26-110-B, E26-130-B, E26-150-B, E26-175-B, E26-220-B,)

CLEARED

Nov 29, 2023
161 days to decision

K231821 · Product code: **KRA** · Cardiovascular
Source: https://www.510kdatabase.net/k231821/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Continuous Flush (KRA)
Date received	Jun 21, 2023
Decision date	Nov 29, 2023
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Transit Scientific, LLC**
Location	Salt Lake City, UT, US
Contact	Jennifer Arnold
510(k) history	5 submissions · 5 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**University of Utah, Center For Medical Innovation**
Contact	Spencer Walker

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