

K180040 NC TREK™ RX Coronary Dilatation CatheterAug 24, 2018
231 days to decisionK180040 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k180040/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Jan 5, 2018
Decision date	Aug 24, 2018
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary
Other names	NC TREK™ OTW Coronary Dilatation Catheter; TREK™ RX Coronary Dilatation Catheter; TREK™ OTW Coronary Dilatation Catheter; MINI TREK™ RX Coronary Dilatation Catheter; MINI TREK™ OTW Coronary Dilatation Catheter; MINI TREK™ II OTW Coronary Dilatation Catheter

APPLICANT

Company	Abbott Vascular
Location	S,Mta Clara, CA, US
Contact	Emily Zhao
510(k) history	30 submissions · 30 cleared · 2009-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180040/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026