

**K193322 NovaCross CTO Microcatheter**Apr 2, 2020  
122 days to decisionK193322 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k193322/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 2, 2019
Decision date	Apr 2, 2020
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>Nitiloop , Ltd.</b>
Location	Herzliya, IL
Contact	Amir Pansky
510(k) history	4 submissions · 4 cleared · 2015-2020

**REGULATORY CONSULTANT**

Consulting firm	<b>Boston Biomedical Associates, LLC</b>
Contact	Wanda Carpinella

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

**CLINICAL EVIDENCE - NCT02477579****A Prospective, Multi-Center, Pivotal Study to Evaluate the Safety and Effectiveness of the NovaCross™ Microcatheter in Facilitating Crossing Chronic Total Occlusion (CTO) Coronary Lesions**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	145 patients (actual)
Study sites	5 sites
Condition studied	Chronic Total Occlusion of Coronary Artery
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Aug 10, 2017
Sponsor	Nitiloop Ltd. (Industry)

**Primary outcome****MACE****Secondary outcome**

1. The ability to cross the lesion with a guidewire in the true lumen, effectively dilate the CTO lesion, and place a coronary stent with residual lumen stenosis of less than 30% while restoring antegrade TIMI 3 flow.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT02477579](https://clinicaltrials.gov/study/NCT02477579)