

K152202 Intermediate Catheter, 105 cm, Intermediate Catheter, 115cm, Intermediate Catheter , 125cmDec 14, 2015
130 days to decisionK152202 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k152202/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 6, 2015
Decision date	Dec 14, 2015
Days to decision	130 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Tni Manufacturing, Inc.
Location	Sunrise, FL, US
Contact	Daniel Sablyak
510(k) history	2 submissions · 2 cleared · 2015-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152202/> 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 June 3, 2026