

**K152876 LONG SHEATH OR LS, 70 CM, LONG SHEATH OR LS,
80 CM, LONG SHEATH OR LS, 90 CM**Jan 8, 2016
100 days to decisionK152876 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k152876/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 30, 2015
Decision date	Jan 8, 2016
Days to decision	100 days
Third-party review	No
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/k152876/> 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