

K181031 TSI Transseptal IntroducerOct 26, 2018
191 days to decisionK181031 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k181031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 18, 2018
Decision date	Oct 26, 2018
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pressure Products Medical Device Manufacturing, LLC
Location	Morton, PA, US
Contact	Andrew Armour
510(k) history	9 submissions · 9 cleared · 2017-2026

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