

**K181088 TSP Crosser Transseptal Access System**Sep 28, 2018  
156 days to decisionK181088 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k181088/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 25, 2018
Decision date	Sep 28, 2018
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Transseptal Solutions , Ltd.</b>
Location	Natanya, IL
Contact	Mary P. LeGraw
510(k) history	1 submissions · 1 cleared · 2018-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>Boston Biomedical Associates</b>
Contact	Mary P. LeGraw

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

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