

K261745 LightningWire Transseptal Puncture System (TPS)Jun 26, 2026
30 days to decisionK261745 · Product code: **DXF** · CardiovascularSource: <https://www.510kdatabase.net/k261745/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Septostomy (DXF)
Date received	May 27, 2026
Decision date	Jun 26, 2026
Days to decision	30 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	ElectroWire Medical
Location	Lexington, SC, US
Contact	Robert (Bobby) Leonardi
510(k) history	1 submissions · 1 cleared · 2026-2026

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