

**K243233 esolution® Esophageal Retractor**Nov 9, 2024  
31 days to decisionK243233 · Product code: **QXU** · Cardiovascular  
Source: <https://www.510kdatabase.net/k243233/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Esophageal Protection Device For Use In Percutaneous Cardiac Catheter Ablation Procedures, Mechanical Deviation (QXU)
Date received	Oct 9, 2024
Decision date	Nov 9, 2024
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>S4 Medical Corp.</b>
Location	Chagrin Falls, OH, US
Contact	William Fuller
510(k) history	2 submissions · 1 cleared · 2023-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243233/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026