

**K240925 DuraGraft Vascular Conduit Solution**May 1, 2024  
27 days to decisionK240925 · Product code: **QEJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k240925/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Flushing Solution For Short Term Storage Of Veins At Room Temperature During Coronary Artery Bypass Graft Surgeries (QEJ)
Date received	Apr 4, 2024
Decision date	May 1, 2024
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Marizyme</b>
Location	Jupiter, FL, US
Contact	Catherine Pachuk
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	John Smith

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240925/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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