

**K242255 Qitexio® 4-Way Stopcock (QIT014)**Apr 29, 2025  
272 days to decisionK242255 · Product code: **FMG** · General Hospital  
Source: <https://www.510kdatabase.net/k242255/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stopcock, I.v. Set (FMG)
Date received	Jul 31, 2024
Decision date	Apr 29, 2025
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medex</b>
Location	Saint-Priest, FR
Contact	Guylaine Casses
510(k) history	2 submissions · 2 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Guerbet, LLC</b>
Contact	Haewon Park

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242255/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026