FDA 510(k) Premarket Notification

CLEARED

K242255 Qitexio® 4-Way Stopcock (QIT014)

Apr 29, 2025
272 days to decision

K242255 · Product code: **FMG** · General Hospital
Source: https://www.510kdatabase.net/k242255/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Guerbet, LLC**
Contact	Haewon Park

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