

**K211204 SafePort(TM) Manifold (or Stopcock)**Sep 15, 2022  
511 days to decisionK211204 · Product code: **FMG** · General Hospital  
Source: <https://www.510kdatabase.net/k211204/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stopcock, I.v. Set (FMG)
Date received	Apr 22, 2021
Decision date	Sep 15, 2022
Days to decision	511 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Elcam Medical Acal</b>
Location	Phoenix, AZ, US
Contact	Avital Levertov
510(k) history	16 submissions · 16 cleared · 2003-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211204/> 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 26, 2026