

**K123084 DISPOSABLE HIGH PRESSURE  
STOPCOCK/MANIFOLD MODEL HP STOPCOCK, MP  
STOPCOCK, HP MANIFOLD, PHP MANIFOLD**May 23, 2013  
234 days to decisionK123084 · Product code: **FMG** · General Hospital  
Source: <https://www.510kdatabase.net/k123084/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Stopcock, I.v. Set (FMG)           |
| Date received         | Oct 1, 2012                        |
| Decision date         | May 23, 2013                       |
| Days to decision      | 234 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Elcam Medical Acal</b>               |
| Location       | Phoenix, AZ, US                         |
| Contact        | AHARON COHEN                            |
| 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/k123084/>; 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