FDA 510(k) Premarket Notification

**CLEARED**

# K111016 SAFEPORT MANIFOLD (TM) (OR STOPCOCK)

Jun 9, 2011
58 days to decision

K111016 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k111016/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Apr 12, 2011 |
| Decision date | Jun 9, 2011 |
| Days to decision | 58 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Elcam Medical Acal** |
| Location | Phoenix, AZ, US |
| Contact | NATASHA EVRONYAN |
| 510(k) history | 16 submissions · 16 cleared · 2003-2023 |