FDA 510(k) Premarket Notification

# K060580 K-SHIELD PORT ACCESS INFUSION SET

**CLEARED**

Jun 6, 2006
92 days to decision

K060580 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k060580/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Mar 6, 2006 |
| Decision date | Jun 6, 2006 |
| Days to decision | 92 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Kawasumi Laboratories, Inc.** |
| Location | Washington, DC, US |
| Contact | JACK PAVLO |
| 510(k) history | 11 submissions · 11 cleared · 2002-2019 |