FDA 510(k) Premarket Notification

# K021395 MODIFICATION TO 30 EXTENSION SET

**CLEARED**

May 13, 2002
11 days to decision

K021395 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k021395/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | May 2, 2002 |
| Decision date | May 13, 2002 |
| Days to decision | 11 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Churchill Medical Systems, Inc.** |
| Location | Horsham, PA, US |
| Contact | KEVIN PALUCH |
| 510(k) history | 12 submissions · 12 cleared · 1988-2004 |