FDA 510(k) Premarket Notification

# K030032 CROSSEAL APPLICATION DEVICE

**CLEARED**

Mar 21, 2003
77 days to decision

K030032 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k030032/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received | Jan 3, 2003 |
| Decision date | Mar 21, 2003 |
| Days to decision | 77 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Omrix Biopharmaceuticals, Inc.** |
| Location | Warrington, VA, US |
| Contact | SUE BHADARE |
| 510(k) history | 1 submissions · 1 cleared · 2003-2003 |