FDA 510(k) Premarket Notification

# K980631 EMBOL-X AORTIC OCCLUSION AND CARDIOPLEGIA CANNULA

**CLEARED**

Feb 2, 1999
349 days to decision

K980631 · Product code: **DXC** · Cardiovascular
Source: https://www.510kdatabase.net/k980631/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Clamp, Vascular (DXC) |
| Date received | Feb 18, 1998 |
| Decision date | Feb 2, 1999 |
| Days to decision | 349 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Embol-X, Inc.** |
| Location | Mountain View, CA, US |
| Contact | JEAN CHANG |
| 510(k) history | 4 submissions · 4 cleared · 1999-2003 |