FDA 510(k) Premarket Notification

**CLEARED**

# K022042 MODIFICATION TO CARDEON ASCENDING BALLOON CANNULA (ABC)

Sep 3, 2002
71 days to decision

K022042 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k022042/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF) |
| Date received | Jun 24, 2002 |
| Decision date | Sep 3, 2002 |
| Days to decision | 71 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Cardeon Corp.** |
| Location | Cupertino, CA, US |
| Contact | JANE BEGGS |
| 510(k) history | 6 submissions · 6 cleared · 2000-2004 |