

K962154 CARBOMEDICS HANDLEAug 27, 1996
84 days to decisionK962154 · Product code: **DTJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k962154/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Holder, Heart-valve, Prosthesis (DTJ) |
| Date received | Jun 4, 1996 |
| Decision date | Aug 27, 1996 |
| Days to decision | 84 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Carbomedics, Inc. |
| Location | Mchenry, IL, US |
| Contact | JOY FISHER-SHUGART |
| 510(k) history | 22 submissions · 18 cleared · 1979-1997 |

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