

K960923 CARBOMEDICS MITRAL ROTATORApr 29, 1996
54 days to decisionK960923 · Product code: **MOP** · Cardiovascular
Source: <https://www.510kdatabase.net/k960923/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Rotator, Prosthetic Heart Valve (MOP) |
| Date received | Mar 6, 1996 |
| Decision date | Apr 29, 1996 |
| Days to decision | 54 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k960923/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 22, 2026