

K970375 ANNULOFLO SYSTEMJul 25, 1997
172 days to decisionK970375 · Product code: **KRH** · Cardiovascular
Source: <https://www.510kdatabase.net/k970375/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------|
| Decision | Substantially Equivalent - ST |
| Submission type | Traditional |
| Device classification | Ring, Annuloplasty (KRH) |
| Date received | Feb 3, 1997 |
| Decision date | Jul 25, 1997 |
| Days to decision | 172 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970375/>; 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