

K992056 ANNULOFLEX ANNULOPLASTY SYSTEM, MODEL AF800Oct 12, 1999
116 days to decisionK992056 · Product code: **KRH** · Cardiovascular
Source: <https://www.510kdatabase.net/k992056/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ring, Annuloplasty (KRH)
Date received	Jun 18, 1999
Decision date	Oct 12, 1999
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sulzer Carbomedics, Inc.
Location	Austin, TX, US
Contact	ROBERT M WOLFARTH
510(k) history	8 submissions · 8 cleared · 1998-2002

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