

**K023185 ANNULOFLEX ANNUOPLASTY SYSTEM, MODEL AF
800**Dec 17, 2002
84 days to decisionK023185 · Product code: **KRH** · Cardiovascular
Source: <https://www.510kdatabase.net/k023185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ring, Annuloplasty (KRH)
Date received	Sep 24, 2002
Decision date	Dec 17, 2002
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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