

**K980534 DURAN FLEXIBLE ANNULOPLASTY RING MODEL
NUMBER H608H**Apr 30, 1998
78 days to decisionK980534 · Product code: **KRH** · Cardiovascular
Source: <https://www.510kdatabase.net/k980534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ring, Annuloplasty (KRH)
Date received	Feb 11, 1998
Decision date	Apr 30, 1998
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	The Heart Valve Div. Medtronic Cardiovascular Surg
Location	Minneapolis, MN, US
Contact	JEAN CHAMPION
510(k) history	5 submissions · 4 cleared · 1991-1998

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