

K912554 ANNULOPLASTY RINGS, MODEL 4400 MIRTAL AND 4500 TRISep 9, 1991
90 days to decisionK912554 · Product code: **KRH** · Cardiovascular
Source: <https://www.510kdatabase.net/k912554/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ring, Annuloplasty (KRH)
Date received	Jun 11, 1991
Decision date	Sep 9, 1991
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Baxter Healthcare Corp
Location	Mchenry, IL, US
Contact	Roberta Hines
510(k) history	505 submissions · 496 cleared · 1977-2019

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