

K952638 4.5F IMAGECATH CORONARY ANGIOSCOPE, MODEL COV45 [SUBSEQUENTLY REFERRED TO AS THE MODIFIED ANGIOSCOPE]Jul 28, 1995
49 days to decisionK952638 · Product code: LYK · Cardiovascular
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Angioscope (LYK)
Date received	Jun 9, 1995
Decision date	Jul 28, 1995
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baxter Edwards
Location	Irvine, CA, US
Contact	RIC RUEDY
510(k) history	11 submissions · 10 cleared · 1993-2000

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