

K831403 LOW PROFILE STEERABLE BALLOON DILATAJun 8, 1983
37 days to decisionK831403 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k831403/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 2, 1983
Decision date	Jun 8, 1983
Days to decision	37 days
Third-party review	No

APPLICANT

Company	Advanced Cardiovascular Systems, Inc.
Location	Santa Clara, CA, US
510(k) history	103 submissions · 100 cleared · 1982-2002

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