

K833690 COAXIAL BALLOON URETHRAL DILATORNov 29, 1983
42 days to decisionK833690 · Product code: **FAA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k833690/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Replacer, Urethral (FAA)
Date received	Oct 18, 1983
Decision date	Nov 29, 1983
Days to decision	42 days
Third-party review	No

APPLICANT

Company	American Edwards Laboratories
Location	Walker, MI, US
510(k) history	89 submissions · 88 cleared · 1980-1987

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Device record: <https://www.510kdatabase.net/k833690/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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