

K800462 PERCUTANEOUS INTRODUCER SETMar 19, 1980
19 days to decisionK800462 · Product code: **DRE** · CardiovascularSource: <https://www.510kdatabase.net/k800462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Feb 29, 1980
Decision date	Mar 19, 1980
Days to decision	19 days
Third-party review	No

APPLICANT

Company	Medical Components, Inc.
Location	Mchenry, IL, US
510(k) history	63 submissions · 55 cleared · 1980-2025

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Device record: <https://www.510kdatabase.net/k800462/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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