

K945586 FLEXIBLE DILATING SHEATHApr 4, 1997
872 days to decisionK945586 · Product code: **DRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k945586/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Nov 14, 1994
Decision date	Apr 4, 1997
Days to decision	872 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Med Institute, Inc.
Location	West Lafayette, IN, US
Contact	NEAL E FEARNOT
510(k) history	26 submissions · 23 cleared · 1990-2000

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