

**K070749 ESTECH PERCUTANEOUS INSERTION DILATOR KIT**Oct 24, 2007  
219 days to decisionK070749 · Product code: **DRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k070749/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Mar 19, 2007
Decision date	Oct 24, 2007
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coombs Medical Device Consulting</b>
Location	Alameda, CA, US
Contact	CRAIG COOMBS
510(k) history	1 submissions · 1 cleared · 2007-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k070749/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 26, 2026