

**K973007 DATASCOPE'S 10 FR. FLEXISHEATH  
PERCUTANEOUS INTRODUCER**Nov 6, 1997  
85 days to decisionK973007 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k973007/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 13, 1997
Decision date	Nov 6, 1997
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Datascope Corp.</b>
Location	Mchenry, IL, US
Contact	WHITNEY TORNING
510(k) history	136 submissions · 135 cleared · 1976-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973007/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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