

**K081049 FLEXCATH STEERABLE SHEATH & DILATOR,
MODELS 3FC10, 3FC12**Jun 27, 2008
74 days to decisionK081049 · Product code: **DRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k081049/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Steerable (DRA)
Date received	Apr 14, 2008
Decision date	Jun 27, 2008
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cryocath Technologies, Inc.
Location	Kirkland, CA
Contact	FRED MILDER
510(k) history	6 submissions · 6 cleared · 2003-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081049/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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