FDA 510(k) Premarket Notification

CLEARED

K081049 FLEXCATH STEERABLE SHEATH & DILATOR, MODELS 3FC10, 3FC12

Jun 27, 2008
74 days to decision

K081049 · 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