

K042308 SHEATH-IN-SHEATH CATHETER, 18FR, MODEL S00018Feb 17, 2005
176 days to decisionK042308 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k042308/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 25, 2004
Decision date	Feb 17, 2005
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary
Other names	SHEATH-IN-SHEATH CATHETER, 6 FR., MODEL S00019

APPLICANT

Company	Facile Medical, Inc.
Location	Mission Viejo, CA, US
Contact	ALBERT REGO
510(k) history	1 submissions · 1 cleared · 2005-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042308/> Data sourced from FDA 510(k) public records (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. - Generated July 2, 2026