

K153533 Tearaway Introducer Sheath, MicroSlide Tearaway Introducer

Jul 5, 2016
209 days to decision

K153533 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k153533/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 9, 2015
Decision date	Jul 5, 2016
Days to decision	209 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Galt Medical Corp.
Location	Garland, TX, US
Contact	DAVID DERRICK
510(k) history	14 submissions · 12 cleared · 1999-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k153533/> 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 June 21, 2026