

K052557 SUPER SHEATH INTRODUCER SHEATHJan 17, 2006
123 days to decisionK052557 · Product code: **DRE** · CardiovascularSource: <https://www.510kdatabase.net/k052557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Sep 16, 2005
Decision date	Jan 17, 2006
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Togo Medikit Co., Ltd.
Location	Chiyoda-Ku Tokyo101 Japan, JP
Contact	HEIDI M ERICKSON
510(k) history	17 submissions · 17 cleared · 1986-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052557/> 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 May 26, 2026