FDA 510(k) Premarket Notification

K052557 SUPER SHEATH INTRODUCER SHEATH

CLEARED

Jan 17, 2006
123 days to decision

K052557 · Product code: **DRE** · Cardiovascular
Source: 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