FDA 510(k) Premarket Notification

K241230 Super Sheath Introducer Sheath S-3N5/1005 S-3N7/1006 S-3W5/1007 S-3W7/1008

CLEARED

Sep 17, 2024
138 days to decision

K241230 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k241230/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 2, 2024
Decision date	Sep 17, 2024
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Mic International Corp.**
Contact	Fumiaki Kanai

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov