

**K241230 Super Sheath Introducer Sheath S-3N5/1005
S-3N7/1006 S-3W5/1007 S-3W7/1008**Sep 17, 2024
138 days to decisionK241230 · 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241230/> 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 13, 2026