

K121504 SUPER SHEATH INTRODUCER SHEATH AND SUPER SHEATH INTRODUCER SHEATH SETSSep 27, 2012
129 days to decisionK121504 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k121504/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 21, 2012
Decision date	Sep 27, 2012
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121504/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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