

K200379 Super SheathMar 19, 2020
30 days to decisionK200379 · Product code: **DRE** · CardiovascularSource: <https://www.510kdatabase.net/k200379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Feb 18, 2020
Decision date	Mar 19, 2020
Days to decision	30 days
Third-party review	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

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