

**K190001 Supercath 5**Sep 20, 2019  
261 days to decisionK190001 · Product code: **FOZ** · General Hospital  
Source: <https://www.510kdatabase.net/k190001/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jan 2, 2019
Decision date	Sep 20, 2019
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190001/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026