

**K193158 ACENT™ Central Venous Catheter**Nov 24, 2020  
376 days to decisionK193158 · Product code: **FOZ** · General HospitalSource: <https://www.510kdatabase.net/k193158/>**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	Nov 14, 2019
Decision date	Nov 24, 2020
Days to decision	376 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Global Medikit Limited</b>
Location	Dehradun, IN
Contact	Mahendra Singh
510(k) history	2 submissions · 2 cleared · 2020-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193158/> 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 27, 2026