

**K231589 Blood Tubing Lines for Hemodialysis AV06C-E**Jul 28, 2023  
57 days to decisionK231589 · Product code: **KOC** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k231589/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Blood Circuit, Hemodialysis (KOC)
Date received	Jun 1, 2023
Decision date	Jul 28, 2023
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>NIKKISO CO., LTD.</b>
Location	Mchenry, IL, US
Contact	Satoko Hina
510(k) history	11 submissions · 11 cleared · 1981-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mic International</b>
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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231589/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026