

K242176 BLOOD TUBING LINES FOR HEMODIALYSIS AL Series (Archloop) BLOOD TUBING LINES FOR HEMODIALYSIS C18 Series (AL-ADC-E(U), AL-CDC-E(U), C18RDC-E(U), C18BDD-E(U), C18SFD-E(U))May 15, 2025
295 days to decisionK242176 · Product code: **KOC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k242176/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Blood Circuit, Hemodialysis (KOC)
Date received	Jul 24, 2024
Decision date	May 15, 2025
Days to decision	295 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Mic International
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)

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