

**K242479 BLOOD TUBING LINES FOR HEMODIALYSIS AL Series (Archloop) BLOOD TUBING LINES FOR HEMODIALYSIS C18 Series AL-ADC-PU, AL-CDC-PU, C18RDC-PU, C18BDD-PU, C18SFD-PU**May 15, 2025  
267 days to decisionK242479 · Product code: **KOC** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k242479/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | Accessories, Blood Circuit, Hemodialysis (KOC) |
| Date received         | Aug 21, 2024                                   |
| Decision date         | May 15, 2025                                   |
| Days to decision      | 267 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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242479/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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