

K251442 TIANYI Extracorporeal Blood Tubing Set (TY-NDEO-A1)Oct 2, 2025
146 days to decisionK251442 · Product code: **FJK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k251442/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Tubing, Blood, With And Without Anti-regurgitation Valve (FJK)
Date received	May 9, 2025
Decision date	Oct 2, 2025
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ningbo Tianyi Medical Appliance Co., Ltd.
Location	Ningbo, CN
Contact	Wenyu Zhang
510(k) history	3 submissions · 3 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Suzhou Device Innovation Medical Consulting Co., Ltd.
Contact	Mike Gu

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.netDevice record: <https://www.510kdatabase.net/k251442/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026