

K202796 SANSIN Tubing Sets for HemodialysisSep 6, 2021
348 days to decisionK202796 · Product code: **FJK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k202796/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Tubing, Blood, With And Without Anti-regurgitation Valve (FJK)
Date received	Sep 23, 2020
Decision date	Sep 6, 2021
Days to decision	348 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangxi Sanxin Medtec Co., Ltd.
Location	Nanchang, CN
Contact	Shuiqing Sun
510(k) history	3 submissions · 3 cleared · 2015-2021

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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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