

K210621 Oral/Enteral SyringeApr 28, 2021
57 days to decisionK210621 · Product code: **PNR** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k210621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteral Syringes With Enteral Specific Connectors (PNR)
Date received	Mar 2, 2021
Decision date	Apr 28, 2021
Days to decision	57 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	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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210621/> 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 25, 2026