

**K211025 Oral/Enteral Syringe with ENFit connector**Jun 30, 2021  
85 days to decisionK211025 · Product code: **PNR** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k211025/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteral Syringes With Enteral Specific Connectors (PNR)
Date received	Apr 6, 2021
Decision date	Jun 30, 2021
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
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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