

**K203613 ENFit Reusable Enteral Syringe**Aug 27, 2021  
260 days to decisionK203613 · Product code: **PNR** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k203613/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteral Syringes With Enteral Specific Connectors (PNR)
Date received	Dec 10, 2020
Decision date	Aug 27, 2021
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shantou Wealy Medical Instrument Co.,Ltd</b>
Location	Echo, OR, US
Contact	Yang Songling
510(k) history	6 submissions · 6 cleared · 2012-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Sungo Management Consulting Company Limited.</b>
Contact	Eva Li

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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203613/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026