

K250389 XNY Disposable Gastric Calibration TubeApr 10, 2025
58 days to decisionK250389 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Feb 11, 2025
Decision date	Apr 10, 2025
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Xin Neng Yuan Medical Stapler Co.,Ltd
Location	Changzhou, CN
Contact	Hong Zhou
510(k) history	3 submissions · 3 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
Contact	Jenny Xia

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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