

K190502 ENFit Oral / Enteral SyringeAug 6, 2019
158 days to decisionK190502 · Product code: **PNR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190502/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteral Syringes With Enteral Specific Connectors (PNR)
Date received	Mar 1, 2019
Decision date	Aug 6, 2019
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Caina Medical Co.,Ltd
Location	Jiangyin, CN
Contact	Xinyan Ruan
510(k) history	21 submissions · 21 cleared · 2018-2024

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

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