

K211661 ENFit enteral syringes (NUTRIFIT)Feb 28, 2022
272 days to decisionK211661 · Product code: **PNR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k211661/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteral Syringes With Enteral Specific Connectors (PNR)
Date received	Jun 1, 2021
Decision date	Feb 28, 2022
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pentaferte Italia S.R.L.
Location	Campfi, IT
Contact	Rosa Di Gioia
510(k) history	3 submissions · 3 cleared · 2017-2022

REGULATORY CONSULTANT

Consulting firm	Vygon USA
Contact	Stephanie Rose

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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