

**K243652 Monoject™ Enteral Syringe with ENFit Connector
(401SE)**Dec 19, 2024
23 days to decisionK243652 · Product code: **PNR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k243652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enteral Syringes With Enteral Specific Connectors (PNR)
Date received	Nov 26, 2024
Decision date	Dec 19, 2024
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Monoject™ Enteral Syringe with ENFit Connector (403SE); Monoject™ Enteral Syringe with ENFit Connector (406SE); Monoject™ Enteral Syringe with ENFit Connector (412SE); Monoject™ Enteral Syringe with ENFit Connector (435SE); Monoject™ Enteral Syringe with ENFit Connector (460SE)

APPLICANT

Company	Cardinalhealth
Location	Mcgaw Park, IL, US
Contact	Kathleen Di Leo
Website	http://www.cardinalhealth.com
510(k) history	32 submissions · 32 cleared · 2003-2026

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