

K213258 Nasogastric Feeding Tubes - ENFit Port - PVCJun 9, 2022
252 days to decisionK213258 · Product code: **PIF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k213258/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gastrointestinal Tubes With Enteral Specific Connectors (PIF) |
| Date received | Sep 30, 2021 |
| Decision date | Jun 9, 2022 |
| Days to decision | 252 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cair Lgl |
| Location | New York, NY, US |
| Contact | Irving L. Wiesen |
| 510(k) history | 8 submissions · 8 cleared · 2014-2024 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------|
| Consulting firm | Vesco Medical |
| Contact | Glenn Brunner |

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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