

K250481 Extension Feeding Set with ENFit™ ConnectorsApr 18, 2025
58 days to decisionK250481 · Product code: **PIF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250481/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Tubes With Enteral Specific Connectors (PIF)
Date received	Feb 19, 2025
Decision date	Apr 18, 2025
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	SKY Medical, a.s.
Location	Samorin, SK
Contact	Yulia Surinova
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250481/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026