

K190327 ENConnect 40 mm Screw Cap to ENPlus AdapterApr 9, 2019
55 days to decisionK190327 · Product code: **PIF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190327/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Tubes With Enteral Specific Connectors (PIF)
Date received	Feb 13, 2019
Decision date	Apr 9, 2019
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cedic S.R.L.
Location	Peschiera Borromeo, IT
Contact	Tiziana Melis
510(k) history	7 submissions · 7 cleared · 2005-2019

REGULATORY CONSULTANT

Consulting firm	Koelper Consulting, LLC
Contact	Crystal Koelper

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190327/> 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 June 25, 2026