

K153550 FTRD System SetOct 12, 2016
306 days to decisionK153550 · Product code: **PKL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k153550/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Dec 11, 2015
Decision date	Oct 12, 2016
Days to decision	306 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ovesco Endoscopy AG
Location	Karlsruhe, DE
Contact	MARC O. SCHURR
510(k) history	14 submissions · 13 cleared · 2010-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153550/> 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 24, 2026