

K170867 FTRD System SetJul 25, 2017
124 days to decisionK170867 · Product code: **PKL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k170867/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Mar 23, 2017
Decision date	Jul 25, 2017
Days to decision	124 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

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