

**K241858 BARS Set (100.60)**Aug 26, 2024  
60 days to decisionK241858 · Product code: **PKL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k241858/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Jun 27, 2024
Decision date	Aug 26, 2024
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ovesco Endoscopy AG</b>
Location	Karlsruhe, DE
Contact	Antonio Caputo
510(k) history	14 submissions · 13 cleared · 2010-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Novineon CRO GmbH</b>
Contact	Amko Groeneveld

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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