

**K251562 OTSCneo System Set (100.03n-14n, 100.27n-31n)**Dec 18, 2025  
210 days to decisionK251562 · Product code: **PKL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k251562/>**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	May 22, 2025
Decision date	Dec 18, 2025
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Novineon CRO GmbH</b>
Contact	Natalja Klymov

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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