

K101428 OTSC (OVER-THE SCOPE-CLIP) SYSTEM SETDec 1, 2010
194 days to decisionK101428 · Product code: **PKL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k101428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	May 21, 2010
Decision date	Dec 1, 2010
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ovesco Endoscopy AG
Location	Karlsruhe, DE
Contact	ARNE BRIEST
510(k) history	14 submissions · 13 cleared · 2010-2025

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