

K183309 stentfix OTSC System SetOct 22, 2019
327 days to decisionK183309 · Product code: **PKL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k183309/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Nov 29, 2018
Decision date	Oct 22, 2019
Days to decision	327 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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