

K200684 gastroduodenal FTRD SetJun 2, 2020
78 days to decisionK200684 · Product code: **PKL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k200684/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Mar 16, 2020
Decision date	Jun 2, 2020
Days to decision	78 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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