

K182664 FiXcisionDec 7, 2018
73 days to decisionK182664 · Product code: **KOA** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k182664/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Instruments, G-u, Manual (and Accessories) (KOA)
Date received	Sep 25, 2018
Decision date	Dec 7, 2018
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Agency For Medical Innovations GmbH
Location	Feldkirch, AT
Contact	Martin Hohlrieder
510(k) history	4 submissions · 4 cleared · 2015-2021

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