

K221385 LiftUp (Ref. Nr.: 200.56.01), LiftUp Kit (Ref. Nr.: 200.56.02)Aug 11, 2022
90 days to decisionK221385 · Product code: PLL · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k221385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Submucosal Injection Agent (PLL)
Date received	May 13, 2022
Decision date	Aug 11, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	Novineon CRO GmbH
Contact	Dragana Galevska

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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