FDA 510(k) Premarket Notification

CLEARED

K221385 LiftUp (Ref. Nr.: 200.56.01), LiftUp Kit (Ref. Nr.: 200.56.02)

Aug 11, 2022
90 days to decision

K221385 · 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