FDA 510(k) Premarket Notification

K241888 Single-use Balloon Dilatation Catheter

CLEARED

Dec 20, 2024
175 days to decision

K241888 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k241888/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jun 28, 2024
Decision date	Dec 20, 2024
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Leo Medical Co., Ltd.**
Location	Changzhou, CN
Contact	Guojun Zhang
510(k) history	2 submissions · 2 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov