FDA 510(k) Premarket Notification

K241591 Blue Eye

CLEARED

Jul 3, 2024
30 days to decision

K241591 · Product code: **PLL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k241591/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Submucosal Injection Agent (PLL)
Date received	Jun 3, 2024
Decision date	Jul 3, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**The Standard Co., Ltd.**
Location	Gunpo-Si, KR
Contact	Seong Nam Kim
510(k) history	2 submissions · 2 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	**LK Consulting Group USA, Inc.**
Contact	Priscilla Chung

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