

K220434 Blue Eye (TS-905)Aug 12, 2022
178 days to decisionK220434 · Product code: **PLL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k220434/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Submucosal Injection Agent (PLL)
Date received	Feb 15, 2022
Decision date	Aug 12, 2022
Days to decision	178 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	Sung 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

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