

**K241591 Blue Eye**Jul 3, 2024  
30 days to decisionK241591 · Product code: **PLL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k241591/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>LK Consulting Group USA, Inc.</b>
Contact	Priscilla Chung

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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