

K232262 LumenEye® X1 endoscope (LX1-SCP-203)Nov 30, 2023
122 days to decisionK232262 · Product code: **FAN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k232262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sigmoidoscope, Rigid, Electrical (FAN)
Date received	Jul 31, 2023
Decision date	Nov 30, 2023
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	LumenEye® X1 consumables (LX1-CSB-201); LumenEye® X1 Consumable Carton (25 Sets) (LX1-CSP-201)

APPLICANT

Company	Surgease Innovations Limited
Location	Lancashire, GB
Contact	Roger Parker
510(k) history	1 submissions · 1 cleared · 2023-2023

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