

K250645 SleeveLUX 24 Anoscope/Proctoscope (P2001)Oct 9, 2025
219 days to decisionK250645 · Product code: **FER** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k250645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anoscope And Accessories (FER)
Date received	Mar 4, 2025
Decision date	Oct 9, 2025
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SleeveLUX 16 Anoscope/Proctoscope (P2002)

APPLICANT

Company	Haemoband Surgical, Ltd.
Location	Bonita Springs, FL, US
Contact	Cathal Donnelly
510(k) history	2 submissions · 2 cleared · 2009-2025

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