

K252703 LithoVue Elite Single-Use Digital Flexible Ureteroscope - Standard with pressure monitoring (M0067940000)

Sep 24, 2025
28 days to decision

K252703 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k252703/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Aug 27, 2025
Decision date	Sep 24, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	LithoVue Elite Single-Use Digital Flexible Ureteroscope - Reverse with pressure monitoring (M0067940500)

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Alexandra Skinner
Website	https://www.bostonscientific.com
510(k) history	229 submissions · 216 cleared · 2005-2026

Boston Scientific Corporation is a global medical device manufacturer headquartered in Marlborough, Massachusetts. The company develops and markets devices across multiple medical specialties. Boston Scientific has received FDA 510(k) clearances from total submissions since its first clearance in 2005. The company maintains active regulatory engagement, with the latest clearance in 2026. Its cleared devices span cardiovascular, radiology, gastroenterology, urology, and surgical specialties, reflecting a broad portfolio of interventional and diagnostic technologies. Recent...