FDA 510(k) Premarket Notification

CLEARED

K241598 LithoVue Elite Single-Use Digital Flexible Ureteroscope - Standard (with pressure monitoring) (M0067940000)

Jul 1, 2024
27 days to decision

K241598 · Product code: **FGB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k241598/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jun 4, 2024
Decision date	Jul 1, 2024
Days to decision	27 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); LithoVue Elite Single-Use Digital Flexible Ureteroscope – Standard (without pressure monitoring) (M0067941000); LithoVue Elite Single-Use Digital Flexible Ureteroscope – Reverse (without pressure monitoring) (M0067941500)

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Matthew Minks
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...