CLEARED

Feb 2, 2023
253 days to decision

K221515 StoneSmart Connect Console, LithoVue Elite Single Use Digital Flexible Ureteroscope Standard w/Pressure Monitoring, LithoVue Elite Single Use Digital Flexible Ureteroscope Reverse w/Pressure Monitoring

K221515 · Product code: **FGB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k221515/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	May 25, 2022
Decision date	Feb 2, 2023
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Tanmay Shukla
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...