FDA 510(k) Premarket Notification

K050403 SPYGLASS DIRECT VISULATION PROBE

CLEARED

Mar 4, 2005
15 days to decision

K050403 · Product code: **ODF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k050403/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mini Endoscope, Gastroenterology-urology (ODF)
Date received	Feb 17, 2005
Decision date	Mar 4, 2005
Days to decision	15 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corp**
Location	San Jose, CA, US
Contact	KATHLEEN MORAHAN
Website	https://www.bostonscientific.com/
510(k) history	432 submissions · 411 cleared · 1988-2024

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...

REGULATORY CONSULTANT

Consulting firm	**Intertek Testing Services**
Contact	DANIEL W LEHTONEN

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov