

K130804 UROMAX ULTRA BALLOON DILATATION CATHETERMay 22, 2013
58 days to decisionK130804 · Product code: **EZN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k130804/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Mar 25, 2013
Decision date	May 22, 2013
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	LAUREN RUSSO
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...

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