FDA 510(k) Premarket Notification

K232162 Autotome Pro RX 39 Sphincterotome

CLEARED

Aug 14, 2023
24 days to decision

K232162 · Product code: **KNS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k232162/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Jul 21, 2023
Decision date	Aug 14, 2023
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Autotome Pro RX 44 Sphincterotome; Jagtome Pro RX 44 Sphincterotome; Jagtome Pro RX 39 Sphincterotome; Dreamtome Pro RX 44 Sphincterotome; Hydratome Pro RX 44 Sphincterotome; Jagtome Revolution Pro RX 39 Sphincterotome

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Stephanie Gorman
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...