

K011965 IMAGER II UROLOGY TORQUE CATHETER, MODEL 40030X1, 40040X1, AND 40050X1Jul 13, 2001
18 days to decisionK011965 · Product code: **KOD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k011965/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Urological (KOD)
Date received	Jun 25, 2001
Decision date	Jul 13, 2001
Days to decision	18 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	ROBERT J MICHALIK
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...