

**K974788 CRE(TM) BALLOON DILATATION CATHETER**Mar 20, 1998  
88 days to decisionK974788 · Product code: **KNQ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k974788/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Esophageal (KNQ)
Date received	Dec 22, 1997
Decision date	Mar 20, 1998
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Boston Scientific Corp</b>
Location	San Jose, CA, US
Contact	DANIEL J DILLION
Website	<a href="https://www.bostonscientific.com/">https://www.bostonscientific.com/</a>
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...