FDA 510(k) Premarket Notification

K993303 SEMI COMPLIANT (SC) 35 BALLOON DILATATION CATHETER

CLEARED

Mar 23, 2000
171 days to decision

K993303 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k993303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Oct 4, 1999
Decision date	Mar 23, 2000
Days to decision	171 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	TERRY A MCGOVERN
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...