

K200483 SpyGlass Discover Digital Catheter, SpyGlass Discover Digital Controller

May 21, 2020
84 days to decision

K200483 · Product code: **FBN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k200483/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Choledochoscope And Accessories, Flexible/rigid (FBN)
Date received	Feb 27, 2020
Decision date	May 21, 2020
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Inderdeep Tiwana
Website	https://www.bostonscientific.com
510(k) history	231 submissions · 218 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...