

**K241683 Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter
(H74939031404020)**Jul 10, 2024
29 days to decisionK241683 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k241683/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jun 11, 2024
Decision date	Jul 10, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031406020); Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031408020); Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031410020); Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031412020); Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031415020); Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H749390314

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Michael McDonagh
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...