

**K060323 ULTRAFLEX PRECISION COLONIC STENT, MODELS
M00557330, MO00557360, M00557380**May 12, 2006
92 days to decisionK060323 · Product code: **MQR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k060323/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stent, Colonic, Metallic, Expandable (MQR) |
| Date received | Feb 9, 2006 |
| Decision date | May 12, 2006 |
| Days to decision | 92 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Boston Scientific Corporation |
| Location | Marlborough, MA, US |
| Contact | JENNIFER KIMBALL |
| 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...

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