

**K140329 RENEGADE HI-FLO MICROCATHETER,
MICROCATHETER KIT, FATHOM SYSTEM, FATHOM KIT**May 15, 2014
94 days to decisionK140329 · Product code: **KRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k140329/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Continuous Flush (KRA) |
| Date received | Feb 10, 2014 |
| Decision date | May 15, 2014 |
| Days to decision | 94 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Boston Scientific |
| Location | San Jose, CA, US |
| Contact | MARK MURPHY |
| Website | http://www.bostonscientific.com/ |
| 510(k) history | 58 submissions · 52 cleared · 2001-2026 |

Boston Scientific is an American biotechnology and biomedical engineering firm headquartered in Marlborough, Massachusetts. The company manufactures medical devices for interventional specialties including cardiology, endoscopy, urology, and oncology. Boston Scientific has received FDA 510(k) clearances from total submissions since 2001. The company maintains active regulatory engagement, with the latest clearance in 2025. Recent cleared devices span cardiovascular, gastroenterology, urology, orthopedic, and general surgery categories, reflecting broad therapeutic focus. ...

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