

K973645 RENEGADE FIBER BRAIDED MICROCATHETERNov 19, 1997
56 days to decisionK973645 · Product code: **KRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k973645/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Continuous Flush (KRA) |
| Date received | Sep 24, 1997 |
| Decision date | Nov 19, 1997 |
| Days to decision | 56 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 | WANDA M CARPINELLA |
| 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...