

**K152842 WALLSTENT RP ENDOPROSTHESIS
TRACHEOBRONCHIAL, WALLSTENT ENDOPROSTHESIS
TRACHEOBRONCHIAL**

May 19, 2016
233 days to decision

K152842 · Product code: **JCT** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k152842/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Tracheal, Expandable (JCT) |
| Date received | Sep 29, 2015 |
| Decision date | May 19, 2016 |
| Days to decision | 233 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Boston Scientific Corporation |
| Location | Marlborough, MA, US |
| Contact | CARAH KUCHARSKI |
| 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...