

K180102 Embozene Color-Advanced MicrospheresApr 19, 2018
93 days to decisionK180102 · Product code: **NOY** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180102/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Agents, Embolic, For Treatment Of Benign Prostatic Hyperplasia (NOY) |
| Date received | Jan 16, 2018 |
| Decision date | Apr 19, 2018 |
| Days to decision | 93 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Boston Scientific |
| Location | San Jose, CA, US |
| Contact | Heidi Shearer |
| 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. ...
