

K150709 ProTrack RF Anchor WireJun 17, 2015
90 days to decisionK150709 · Product code: **DXF** · Cardiovascular
Source: <https://www.510kdatabase.net/k150709/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Septostomy (DXF) |
| Date received | Mar 19, 2015 |
| Decision date | Jun 17, 2015 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Baylis Medical Company, Inc. |
| Location | Mississauga, Ontario, CA |
| Contact | Meghal Khakhar |
| 510(k) history | 24 submissions · 24 cleared · 2012-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150709/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 4, 2026