FDA 510(k) Premarket Notification

**CLEARED**

# K190941 BioCardia 8.5 F Avance Steerable Introducer

May 6, 2019
26 days to decision

K190941 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k190941/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Apr 10, 2019 |
| Decision date | May 6, 2019 |
| Days to decision | 26 days |
| Third-party review | Yes |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Biocardia, Inc.** |
| Location | South San Francisco, CA, US |
| Contact | Kevin DeMartini |
| 510(k) history | 4 submissions · 4 cleared · 2002-2019 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Regulatory Technology Services, LLC** |
| Contact | MARK JOB |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov