

K223766 NUVISION™ NAV Ultrasound CatheterFeb 16, 2023
63 days to decisionK223766 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k223766/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Ultrasound, Intravascular (OBJ) |
| Date received | Dec 15, 2022 |
| Decision date | Feb 16, 2023 |
| Days to decision | 63 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Biosense Webster, Inc. |
| Location | Irvine, CA, US |
| Contact | Sheba Chacko |
| Website | https://www.jnjmedtech.com |
| 510(k) history | 73 submissions · 73 cleared · 1999-2026 |

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