

K181855 RadialSeal Introducer KitJul 26, 2018
15 days to decisionK181855 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k181855/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Jul 11, 2018 |
| Decision date | Jul 26, 2018 |
| Days to decision | 15 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Great Batch Medical |
| Location | Pymouth, MN, US |
| Contact | Phyllis Piet-Hughes |
| 510(k) history | 10 submissions · 10 cleared · 2009-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181855/> 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 May 30, 2026