

**K843719 SINGLE WALL INTRODUCER NEEDLE**Oct 18, 1984  
24 days to decisionK843719 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k843719/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Introducer, Catheter (DYB)         |
| Date received         | Sep 24, 1984                       |
| Decision date         | Oct 18, 1984                       |
| Days to decision      | 24 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Ocean Medical Products, Ltd.</b>   |
| Location       | Mchenry, IL, US                       |
| Contact        | ALAN TAYLOR                           |
| 510(k) history | 9 submissions · 9 cleared · 1981-1988 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k843719/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026