

**K063182 ENPATH MEDICAL VIASEAL VALVED PEELABLE INTRODUCER, MODEL 10866-XXX**

Dec 21, 2006  
63 days to decision

K063182 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k063182/>

**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Introducer, Catheter (DYB)         |
| Date received         | Oct 19, 2006                       |
| Decision date         | Dec 21, 2006                       |
| Days to decision      | 63 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Enpath Medical, Inc.</b>           |
| Location       | Minneapolis, MN, US                   |
| Contact        | JAMES JENKINS                         |
| 510(k) history | 5 submissions · 5 cleared · 2006-2008 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k063182/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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