

**K100163 NUTRISAFE 2 FEEDING TUBES MODEL 362.XXX.  
1362.XXX**Oct 13, 2011  
631 days to decisionK100163 · Product code: **FPD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k100163/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Tube, Feeding (FPD)                |
| Date received         | Jan 20, 2010                       |
| Decision date         | Oct 13, 2011                       |
| Days to decision      | 631 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Vygon Corp.</b>                      |
| Location       | East Rutherford, NJ, US                 |
| Contact        | CINDY VARUGHESE                         |
| 510(k) history | 48 submissions · 46 cleared · 1985-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100163/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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