

**K012665 ULTRA THIN MALE LATEX CONDOM WITH SILICONE LUBRICANT**Nov 9, 2001  
88 days to decisionK012665 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k012665/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Condom (HIS)                       |
| Date received         | Aug 13, 2001                       |
| Decision date         | Nov 9, 2001                        |
| Days to decision      | 88 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Innolates Sdn. Bhd</b>             |
| Location       | Shah Alam, Selangor Darul Ehsan, MY   |
| Contact        | CHANG AH-KAU                          |
| 510(k) history | 9 submissions · 9 cleared · 2000-2006 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012665/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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