

**K080172 BLASTASSIST WITHOUT PHENOL RED, MODEL REF 1215, BLASTASSIST WITH PHENOL RED, MODEL REF 1216**

Dec 18, 2008  
329 days to decision

K080172 · Product code: **MQL** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k080172/>

**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Media, Reproductive (MQL)          |
| Date received         | Jan 24, 2008                       |
| Decision date         | Dec 18, 2008                       |
| Days to decision      | 329 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Medicult A/S</b>                     |
| Location       | San Diego, CA, US                       |
| Contact        | RONALD G LEONARDI                       |
| 510(k) history | 26 submissions · 26 cleared · 2000-2008 |

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

Device record: <https://www.510kdatabase.net/k080172/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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