

**K991471 MEDI-CULT BLASTOCYST FREEZING & THAWING  
PACKS, INTERNAL CATALOG NUMBERS (1012, 1015)**May 9, 2000  
391 days to decisionK991471 · Product code: **MQL** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k991471/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Media, Reproductive (MQL)          |
| Date received         | Apr 14, 1999                       |
| Decision date         | May 9, 2000                        |
| Days to decision      | 391 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/k991471/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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