

**K111715 EMBRYOSCOPE**Aug 11, 2011  
52 days to decisionK111715 · Product code: **MQG** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k111715/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessory, Assisted Reproduction (MQG)
Date received	Jun 20, 2011
Decision date	Aug 11, 2011
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Unisense Fertilittech A/S</b>
Location	Arrhus, DK
Contact	METTE MUNCH
510(k) history	4 submissions · 4 cleared · 2011-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111715/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 6, 2026