

K173264 EmbryoScope+May 11, 2018
212 days to decisionK173264 · Product code: **MQG** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k173264/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accessory, Assisted Reproduction (MQG) |
| Date received | Oct 11, 2017 |
| Decision date | May 11, 2018 |
| Days to decision | 212 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Vitrolife A/S |
| Location | Viby J, DK |
| Contact | Belinda Dueholm |
| 510(k) history | 4 submissions · 4 cleared · 2015-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173264/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026