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## 510(k) Premarket Notification



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|------------------------------------|------------------------------------------------------------------------|
| <b>Device Classification Name</b>  | <a href="#">Device, Fertility Diagnostic, Proceptive</a> <sup>22</sup> |
| <b>510(K) Number</b>               | K200163                                                                |
| <b>Device Name</b>                 | Ava Fertility Tracker                                                  |
| <b>Applicant</b>                   | Ava AG<br>Gustrasse 73<br>Zurich, CH 8055                              |
| <b>Applicant Contact</b>           | Blathnaid Feldman                                                      |
| <b>Correspondent</b>               | Ava AG<br>Gustrasse 73<br>Zurich, CH 8055                              |
| <b>Correspondent Contact</b>       | Blathnaid Feldman                                                      |
| <b>Classification Product Code</b> | <a href="#">LHD</a> <sup>23</sup>                                      |
| <b>Date Received</b>               | 01/22/2020                                                             |
| <b>Decision Date</b>               | 01/19/2021                                                             |
| <b>Decision</b>                    | Substantially Equivalent (SESE)                                        |
| <b>510k Review Panel</b>           | Obstetrics/Gynecology                                                  |
| <b>Summary</b>                     | <a href="#">Summary</a> <sup>24</sup>                                  |
| <b>Type</b>                        | Traditional                                                            |
| <b>Clinical Trials</b>             | <a href="#">NCT03161873</a> <sup>25</sup>                              |
| <b>Reviewed By Third Party</b>     | No                                                                     |
| <b>Combination Product</b>         | No                                                                     |

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Page Last Updated: 09/13/2021

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