

**K192008 LaserShot M, NaviLase**Mar 25, 2020  
240 days to decisionK192008 · Product code: **MRX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k192008/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Assisted Reproduction Laser (MRX)
Date received	Jul 29, 2019
Decision date	Mar 25, 2020
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Vitrolife GmbH</b>
Location	Bruckberg, DE
Contact	Susanne Schweitzer
510(k) history	1 submissions · 1 cleared · 2020-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192008/> 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 28, 2026