

**K081990 LUBRICANO STERILE GEL**Dec 5, 2008  
144 days to decisionK081990 · Product code: **FHX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k081990/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                              |
| Submission type       | Traditional   |
| Device classification | Jelly, Lubricating, For Transurethral Surgical Instrument (FHX) |
| Date received         | Jul 14, 2008  |
| Decision date         | Dec 5, 2008   |
| Days to decision      | 144 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Farco Pharma GmbH</b>              |
| Location       | Washington, DC, US                    |
| Contact        | SETH A MAILHOT                        |
| 510(k) history | 2 submissions · 2 cleared · 2008-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081990/> 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 May 18, 2026