

**K892888 EXTACISER PERINEAL MUSCLE EXERCISER**Oct 5, 1989  
168 days to decisionK892888 · Product code: **HIR** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k892888/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Perineometer (HIR)                 |
| Date received         | Apr 20, 1989                       |
| Decision date         | Oct 5, 1989                        |
| Days to decision      | 168 days                           |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Bivona Medical Technologies</b>      |
| Location       | Mchenry, IL, US                         |
| Contact        | SHAPIRO, M.D.                           |
| 510(k) history | 50 submissions · 50 cleared · 1978-1995 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k892888/>; 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 26, 2026