

**K082916 HRB-127-32 HIGH RESOLUTION BRAIN COIL**Oct 15, 2008  
15 days to decisionK082916 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k082916/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Special                                   |
| Device classification | Coil, Magnetic Resonance, Specialty (MOS) |
| Date received         | Sep 30, 2008                              |
| Decision date         | Oct 15, 2008                              |
| Days to decision      | 15 days                                   |
| Third-party review    | No  |
| Summary / Statement   | Statement                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Invivo</b>                         |
| Location       | Florida, FL, US                       |
| Contact        | JEFF WILKINSON                        |
| 510(k) history | 6 submissions · 6 cleared · 2006-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082916/> 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 17, 2026