

**K111145 ENDO HEAD**Aug 16, 2011  
116 days to decisionK111145 · Product code: **LZY** · Orthopedic  
Source: <https://www.510kdatabase.net/k111145/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Prosthesis, Hip, Hemi-, Femoral, Metal Ball (LZY) |
| Date received         | Apr 22, 2011                                      |
| Decision date         | Aug 16, 2011                                      |
| Days to decision      | 116 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Medacta International</b>            |
| Location       | San Diego, CA, US                       |
| Contact        | ADAM GROSS                              |
| 510(k) history | 39 submissions · 39 cleared · 2011-2016 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111145/> 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