

**K001536 INTER-OP METASUL HOODED AND PROTRUSIO  
ACETABULAR INSERTS**Jul 27, 2000  
71 days to decisionK001536 · Product code: **KWA** · Orthopedic  
Source: <https://www.510kdatabase.net/k001536/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Prosthesis, Hip, Semi-constrained (metal Uncemented Acetabular Component) (KWA) |
| Date received         | May 17, 2000  |
| Decision date         | Jul 27, 2000  |
| Days to decision      | 71 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Sulzer Orthopedics, Inc.</b>         |
| Location       | Austin, TX, US                          |
| Contact        | MITCHELL A DHORITY                      |
| 510(k) history | 45 submissions · 41 cleared · 1997-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001536/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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