

**K854791 BIO-FIT HIP SYSTEM**Feb 27, 1986  
90 days to decisionK854791 · Product code: **KWL** · Orthopedic  
Source: <https://www.510kdatabase.net/k854791/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | Prosthesis, Hip, Hemi-, Femoral, Metal (KWL) |
| Date received         | Nov 29, 1985                                 |
| Decision date         | Feb 27, 1986                                 |
| Days to decision      | 90 days                                      |
| Third-party review    | No   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Richards Medical Co., Inc.</b>       |
| Location       | Walker, MI, US                          |
| Contact        | ROBERT F GAMES                          |
| 510(k) history | 71 submissions · 59 cleared · 1983-1990 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k854791/>, 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 22, 2026