

**K101859 REL-K ARTIFICIAL LIMB PROSTHESIS**Oct 13, 2010  
103 days to decisionK101859 · Product code: **ISY** · Physical Medicine  
Source: <https://www.510kdatabase.net/k101859/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Joint, Knee, External Limb Component (ISY)
Date received	Jul 2, 2010
Decision date	Oct 13, 2010
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Rizzoli Ortopedica S.P.A.</b>
Location	Watertown, MA, US
Contact	DIANE C TIERNAN, MS RAC
510(k) history	1 submissions · 1 cleared · 2010-2010

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101859/> 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 June 20, 2026