

**K130380 ORTHOSENSOR KNEE BALANCER**Jun 13, 2013  
119 days to decisionK130380 · Product code: **ONN** · Orthopedic  
Source: <https://www.510kdatabase.net/k130380/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intraoperative Orthopedic Joint Assessment Aid (ONN)
Date received	Feb 14, 2013
Decision date	Jun 13, 2013
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Orthosensor, Inc.</b>
Location	Appollo Beach, FL, US
Contact	KIMBERLEE WASHBURN
510(k) history	8 submissions · 8 cleared · 2009-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130380/> 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 15, 2026