

**K111443 X12 STERILE REFLECTIVE MARKER SPHERE**Sep 29, 2011  
128 days to decisionK111443 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k111443/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	May 24, 2011
Decision date	Sep 29, 2011
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pinsco Inc. Db a B &amp; L Engineering</b>
Location	Santa Ana, CA, US
Contact	LEE A BARNES
510(k) history	2 submissions · 2 cleared · 1998-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111443/> 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 14, 2026