

**K212023 Virage Navigation System**Aug 27, 2021  
59 days to decisionK212023 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k212023/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 29, 2021
Decision date	Aug 27, 2021
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Zimmer Biomet Spine, Inc.</b>
Location	Broomfield, CO, US
Contact	David Pollard
510(k) history	15 submissions · 15 cleared · 2017-2021

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212023/> 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 26, 2026