

**K183544 Efficient Care 3D Planning**Aug 23, 2019  
246 days to decisionK183544 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k183544/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 20, 2018
Decision date	Aug 23, 2019
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthosoft Inc. (d/b/a) Zimmer CAS</b>
Location	Montreal, CA
Contact	Paul Hardy
Website	<a href="https://www.zimmerbiomet.com">https://www.zimmerbiomet.com</a>
510(k) history	18 submissions · 18 cleared · 2017-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183544/> 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