

**K153306 Imbibe Needle**Dec 18, 2015  
32 days to decisionK153306 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k153306/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	Nov 16, 2015
Decision date	Dec 18, 2015
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Orthovita, Inc.</b>
Location	Malver, PA, US
Contact	LYNN LUNDY
510(k) history	23 submissions · 23 cleared · 2001-2017

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153306/> 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 16, 2026