

**K101312 NUVUE COLORMARK9TM) NEEDLE**Feb 4, 2011  
269 days to decisionK101312 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k101312/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 11, 2010
Decision date	Feb 4, 2011
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Nuvue Therapeutics, Inc.</b>
Location	Fairfax, VA, US
Contact	ROGER S KOLASINSKI
510(k) history	1 submissions · 1 cleared · 2011-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101312/> 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 17, 2026