

**K112827 SHEATHES ULTRASOND GEL**Jun 22, 2012  
268 days to decisionK112827 · Product code: **MUI** · Radiology  
Source: <https://www.510kdatabase.net/k112827/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Sep 28, 2011
Decision date	Jun 22, 2012
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sheathing Technologies, Inc.</b>
Location	Morgan Hill, CA, US
Contact	JENNIFER DOWNING
510(k) history	7 submissions · 7 cleared · 1999-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112827/> 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