

**K163026 Ultra/Phonic Scanning Gel**Jan 9, 2018  
435 days to decisionK163026 · Product code: **MUI** · Radiology  
Source: <https://www.510kdatabase.net/k163026/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Oct 31, 2016
Decision date	Jan 9, 2018
Days to decision	435 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pharmaceutical Innovations, Inc.</b>
Location	Newark, NJ, US
Contact	Shirley J. Bergman
510(k) history	5 submissions · 5 cleared · 1996-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163026/> 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