

**K083284 PIEZOSURGERY MEDICAL**Apr 8, 2009  
152 days to decisionK083284 · Product code: **JDX** · Orthopedic  
Source: <https://www.510kdatabase.net/k083284/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Surgical, Sonic And Accessory/attachment (JDX)
Date received	Nov 7, 2008
Decision date	Apr 8, 2009
Days to decision	152 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Piezosurgery S.R.L.</b>
Location	Rome, IT
Contact	ROGER GRAY
510(k) history	4 submissions · 4 cleared · 2005-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083284/> 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 19, 2026