

**K043408 PIEZOSURGERY DEVICE**Jun 8, 2005  
180 days to decisionK043408 · Product code: **DZI** · Dental  
Source: <https://www.510kdatabase.net/k043408/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Bone, Powered (DZI)
Date received	Dec 10, 2004
Decision date	Jun 8, 2005
Days to decision	180 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Piezosurgery S.R.L.</b>
Location	Rome, IT
Contact	Maria E Donawa
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/k043408/> 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