

**K153296 MEDINAUT Kyphoplasty System**Jul 29, 2016  
259 days to decisionK153296 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k153296/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Nov 13, 2015
Decision date	Jul 29, 2016
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imedicom Co., Ltd.</b>
Location	Gunpo-Si, KR
Contact	Bonggu Ha
510(k) history	6 submissions · 6 cleared · 2016-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153296/> 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 June 28, 2026