

**K172214 Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters**Aug 23, 2017  
30 days to decisionK172214 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k172214/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Jul 24, 2017
Decision date	Aug 23, 2017
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>G-21 S.R.L.</b>
Location	San Possidonio, IT
Contact	Maurizio Foroni
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172214/> Data sourced from FDA 510(k) public records (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