

K152557 Winch Kyphoplasty(15 and 20 mm) 11 Gauge Balloon CathetersFeb 23, 2016
168 days to decisionK152557 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k152557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Sep 8, 2015
Decision date	Feb 23, 2016
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	G21, S.R.L.
Location	San Possidonio, IT
Contact	Maurizio Foroni
510(k) history	12 submissions · 12 cleared · 2015-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152557/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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