

K162283 DCM Kyphoplasty SystemFeb 6, 2017
175 days to decisionK162283 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k162283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Aug 15, 2016
Decision date	Feb 6, 2017
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dragon Crown Medical Co., Ltd.
Location	Jinan, CN
Contact	Zhi Yong Song
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162283/> 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. - Generated May 16, 2026