

K172871 SpineKure Kyphoplasty SystemMay 29, 2018
250 days to decisionK172871 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k172871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Sep 21, 2017
Decision date	May 29, 2018
Days to decision	250 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hanchang Co., Ltd.
Location	Bucheon-Si, KR
Contact	An Kwon Ho
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172871/> 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