FDA 510(k) Premarket Notification

K172871 SpineKure Kyphoplasty System

CLEARED

May 29, 2018
250 days to decision

K172871 · 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