

K143110 GALAXY MIS Screw SystemJun 24, 2015
238 days to decisionK143110 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k143110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 29, 2014
Decision date	Jun 24, 2015
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bm Korea
Location	Gunpo-Si, KR
Contact	JUNE HAN
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143110/> 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 17, 2026