

K143006 GUARDIAN-SG Inflatable Bone Expander SystemJan 16, 2015
88 days to decisionK143006 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k143006/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Oct 20, 2014
Decision date	Jan 16, 2015
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bm Korea Co., Ltd.
Location	Marietta, GA, US
Contact	June Han
510(k) history	5 submissions · 5 cleared · 2011-2015

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