

K192335 TRACKER Kyphoplasty SystemDec 4, 2019
98 days to decisionK192335 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k192335/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Aug 28, 2019
Decision date	Dec 4, 2019
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	GS Medical Co., Ltd.
Location	Seoul, KR
Contact	Andrea Watt
510(k) history	18 submissions · 18 cleared · 2006-2024

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