

K211797 TRACKER Plus Kyphoplasty SystemOct 28, 2021
140 days to decisionK211797 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k211797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Jun 10, 2021
Decision date	Oct 28, 2021
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	RQMIS, Inc.
Contact	Barry Sands

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211797/> 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 26, 2026