FDA 510(k) Premarket Notification

# K211797 TRACKER Plus Kyphoplasty System

**CLEARED**

Oct 28, 2021
140 days to decision

K211797 · 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.gov