FDA 510(k) Premarket Notification

K240350 AnyPlus II Spinal Fixation System

CLEARED

Apr 3, 2024
58 days to decision

K240350 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k240350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 5, 2024
Decision date	Apr 3, 2024
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**GS Medical Co., Ltd.**
Location	Seoul, KR
Contact	Seon Yeon Kim
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