FDA 510(k) Premarket Notification

CLEARED

K221687 Pegasus-X Expandable PLIF System

Jul 27, 2022
47 days to decision

K221687 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k221687/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 10, 2022
Decision date	Jul 27, 2022
Days to decision	47 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 E. Sands

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov