FDA 510(k) Premarket Notification

K223868 PYXIS 3D Titanium Cage System

CLEARED

Apr 26, 2023
124 days to decision

K223868 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k223868/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 23, 2022
Decision date	Apr 26, 2023
Days to decision	124 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k223868/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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