FDA 510(k) Premarket Notification

K241738 PYXIS 3D Titanium Cervical Cage system

CLEARED

Aug 20, 2024
64 days to decision

K241738 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k241738/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jun 17, 2024
Decision date	Aug 20, 2024
Days to decision	64 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