FDA 510(k) Premarket Notification

K231808 QUASAR Standalone ACIF System

CLEARED

Jul 20, 2023
30 days to decision

K231808 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k231808/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jun 20, 2023
Decision date	Jul 20, 2023
Days to decision	30 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