K232292 Peridot-EX Expandable Intervertebral Body Fusion System

CLEARED

Nov 7, 2023
98 days to decision

K232292 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k232292/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 1, 2023
Decision date	Nov 7, 2023
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Gbs Commonwealth Co., Ltd.**
Location	Geumcheon-Gu, KR
Contact	Jimmy Kim
510(k) history	14 submissions · 14 cleared · 2018-2023