FDA 510(k) Premarket Notification

K223654 Medussa-PL Cage

CLEARED

Dec 28, 2022
22 days to decision

K223654 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k223654/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 6, 2022
Decision date	Dec 28, 2022
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medyssey USA, Inc.**
Location	Apple Valley, MN, US
Contact	Youngsu Jang
510(k) history	19 submissions · 19 cleared · 2013-2023

REGULATORY CONSULTANT

Consulting firm	**Eerkie Corp**
Contact	Jeena Mathai

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