FDA 510(k) Premarket Notification

CLEARED

K232996 Iatrical Interbody Lumbar Fusion Systems (Model ALIF, Model TLIF, Model LLIF)

Sep 6, 2024
350 days to decision

K232996 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k232996/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 22, 2023
Decision date	Sep 6, 2024
Days to decision	350 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shanghai Iatrical-Ti Technologies CO , Ltd.**
Location	Shanghai, CN
Contact	Haozhang Zhong
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Manton Business and Technology Services**
Contact	Charles Shen

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