FDA 510(k) Premarket Notification

CLEARED

K201939 GAIA Lumbar Interbody Fusion Device (LIFD) Family

Oct 8, 2020
87 days to decision

K201939 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k201939/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 13, 2020
Decision date	Oct 8, 2020
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Printerprezz**
Location	Fremont, CA, US
Contact	Kishore Karkera
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Nathan Wright

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