FDA 510(k) Premarket Notification

K151408 LOSPA IS Spinal System

CLEARED

Oct 2, 2015
129 days to decision

K151408 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k151408/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 26, 2015
Decision date	Oct 2, 2015
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Corentec Co., Ltd.**
Location	West Cadwell, NJ, US
Contact	GOON HEE LEE
510(k) history	33 submissions · 33 cleared · 2010-2025