FDA 510(k) Premarket Notification

K100544 IMPIX LUMBAR INTERBODY DEVICE

CLEARED

Jul 22, 2010
147 days to decision

K100544 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k100544/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 25, 2010
Decision date	Jul 22, 2010
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medicrea Technologies**
Location	Round Rock, TX, US
Contact	JD WEBB
510(k) history	14 submissions · 14 cleared · 2007-2011