FDA 510(k) Premarket Notification

K121178 TRANSCORP ACIF SYSTEM

CLEARED

Jul 5, 2013
443 days to decision

K121178 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k121178/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Apr 18, 2012
Decision date	Jul 5, 2013
Days to decision	443 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Transcorp, Inc.**
Location	Byron Center, MI, US
Contact	ANDREW RODENHOUSE
510(k) history	4 submissions · 4 cleared · 2010-2013