

K132421 AESCULAP PEEK XP SPINAL IMPLANT SYSTEMJan 22, 2014
170 days to decisionK132421 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k132421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 5, 2013
Decision date	Jan 22, 2014
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aesculap Implant Systems, Inc.
Location	Center Valley, PA, US
Contact	LISA M BOYLE
510(k) history	22 submissions · 22 cleared · 2007-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132421/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026