FDA 510(k) Premarket Notification

K082406 EXPANDABLE PEEK-OPTIMA IMPLANT

CLEARED

Jan 14, 2009
146 days to decision

K082406 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k082406/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 21, 2008
Decision date	Jan 14, 2009
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ebi, L.P.**
Location	Parsippany, NJ, US
Contact	VIVIAN KELLY
510(k) history	95 submissions · 94 cleared · 1997-2010