FDA 510(k) Premarket Notification

K120464 INNESIS PEEK CAGE

CLEARED

Jan 18, 2013
338 days to decision

K120464 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k120464/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 15, 2012
Decision date	Jan 18, 2013
Days to decision	338 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bk Meditech, Co., Ltd.**
Location	Hwasung-Si, Kyunggi-Do, KR
Contact	SHIN KUK YOO
510(k) history	11 submissions · 11 cleared · 2006-2020