FDA 510(k) Premarket Notification

K131612 ANYPLUS

CLEARED

Apr 18, 2014
319 days to decision

K131612 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k131612/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 3, 2013
Decision date	Apr 18, 2014
Days to decision	319 days
Third-party review	No
Summary / Statement	Summary
Other names	ALIF PEEK CAGES, PLIF PEEK CAGES, T-PLIF PEEK CAGES, TLIF PEEK CAGES

APPLICANT

Company	**GS Medical Co., Ltd.**
Location	Seoul, KR
Contact	DONALD W GUTHNER
510(k) history	18 submissions · 18 cleared · 2006-2024