FDA 510(k) Premarket Notification

K123392 AVENIR MULLER STEM

CLEARED

Mar 4, 2013
122 days to decision

K123392 · Product code: **LZO** · Orthopedic
Source: https://www.510kdatabase.net/k123392/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Nov 2, 2012
Decision date	Mar 4, 2013
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer GmbH**
Location	Warsaw, IN, US
Contact	KAREN O'LEARY
510(k) history	43 submissions · 43 cleared · 2004-2023