FDA 510(k) Premarket Notification

CLEARED

K150576 TGM Biolox delta Ceramic Heads

Sep 9, 2015
187 days to decision

K150576 · Product code: **LZO** · Orthopedic
Source: https://www.510kdatabase.net/k150576/

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	Mar 6, 2015
Decision date	Sep 9, 2015
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tgm Medical, Inc.**
Location	El Dorado, CA, US
Contact	Gordon Smith
510(k) history	5 submissions · 5 cleared · 2011-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k150576/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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