

**K121636 ZENITH, FEMORAL STEM ZENITH, DISTAL
CENTRALIZER FOMORAL HEAD ACETABULAR INSERT**Oct 24, 2012
142 days to decisionK121636 · Product code: LPH · Orthopedic
Source: <https://www.510kdatabase.net/k121636/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Jun 4, 2012
Decision date	Oct 24, 2012
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tgm Medical, Inc.
Location	EI Dorado, CA, US
Contact	PRAKASH PAI
510(k) history	5 submissions · 5 cleared · 2011-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121636/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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