FDA 510(k) Premarket Notification

K103497 CERAMIC FEMORAL HEAD

CLEARED

Mar 4, 2011
95 days to decision

K103497 · Product code: **MEH** · Orthopedic
Source: https://www.510kdatabase.net/k103497/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Nov 29, 2010
Decision date	Mar 4, 2011
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**United Orthopedic Corp.**
Location	Hsinchu, TW
Contact	FANG-YUAN HO
510(k) history	20 submissions · 20 cleared · 2000-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k103497/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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