

**K091956 HIGHLY CROSS-LINKED VITAMIN E UHMWPE TIBIAL
INSERTS, MODEL 391/392-09_19-702_712**Sep 28, 2010
454 days to decisionK091956 · Product code: **OIY** · Orthopedic
Source: <https://www.510kdatabase.net/k091956/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer + Additive/metal/polymer + Additive (OIY)
Date received	Jul 1, 2009
Decision date	Sep 28, 2010
Days to decision	454 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Encore Medical, L.P.
Location	Austin, TX, US
Contact	ELIZABETH ONDERLINDE
510(k) history	81 submissions · 81 cleared · 2002-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091956/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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