FDA 510(k) Premarket Notification

K081448 ENCORE SHOULDER REVISION GLENOID

CLEARED

Sep 30, 2008
130 days to decision

K081448 · Product code: **MBF** · Orthopedic
Source: https://www.510kdatabase.net/k081448/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer, Uncemented (MBF)
Date received	May 23, 2008
Decision date	Sep 30, 2008
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k081448/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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