

K040397 MODIFICATION TO CYCLONE ANTERIOR CERVICAL PLATE SYSTEMMay 6, 2004
79 days to decisionK040397 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k040397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Feb 17, 2004
Decision date	May 6, 2004
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040397/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026