

K260796 Tahoe Unicondylar Knee System with TiNbN OvercoatApr 2, 2026
22 days to decisionK260796 · Product code: **HSX** · Orthopedic
Source: <https://www.510kdatabase.net/k260796/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	Mar 11, 2026
Decision date	Apr 2, 2026
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shalby Advanced Technologies, Inc. Db a Consensus Orthopedics
Location	El Dorado Hills, CA, US
Contact	Romil Sheth
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260796/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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