

K243477 Universal Tendon SpacerJan 10, 2025
63 days to decisionK243477 · Product code: **HXA** · Orthopedic
Source: <https://www.510kdatabase.net/k243477/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Tendon, Passive (HXA)
Date received	Nov 8, 2024
Decision date	Jan 10, 2025
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Askorn Medical
Location	Cesson-S?vign?, FR
Contact	Denis Pichon
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243477/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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