

K853438 H-H HUNTER ACTIVE TENDON IMPLANTSep 30, 1985
46 days to decisionK853438 · Product code: **HXA** · Orthopedic
Source: <https://www.510kdatabase.net/k853438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Tendon, Passive (HXA)
Date received	Aug 15, 1985
Decision date	Sep 30, 1985
Days to decision	46 days
Third-party review	No

APPLICANT

Company	Holter-Hausner Intl.
Location	Mchenry, IL, US
Contact	JOHN R BOLLES
510(k) history	42 submissions · 38 cleared · 1978-1988

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853438/>; 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 22, 2026