

K094043 LIGAMENTOTAXORAug 17, 2010
229 days to decisionK094043 · Product code: **HTY** · Orthopedic
Source: <https://www.510kdatabase.net/k094043/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Dec 31, 2009
Decision date	Aug 17, 2010
Days to decision	229 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Arex USA
Location	Collegeville, PA, US
Contact	ELLEN HOKANSON
510(k) history	2 submissions · 2 cleared · 2008-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k094043/> 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 18, 2026