

K935696 ETEX HA HIP REPLACEMENT SYSTEMJul 22, 1994
234 days to decisionK935696 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k935696/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Nov 30, 1993
Decision date	Jul 22, 1994
Days to decision	234 days
Third-party review	No

APPLICANT

Company	Etex Corp.
Location	Cambridge, MA, US
Contact	DOSUK D LEE
510(k) history	18 submissions · 17 cleared · 1994-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935696/>; 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 19, 2026