

**K980632 DURATION II TIBIAL INSERTS - GAS PLASMA
STERILIZATION**Dec 11, 1998
295 days to decisionK980632 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k980632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Feb 19, 1998
Decision date	Dec 11, 1998
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Howmedica Corp.
Location	Mchenry, IL, US
Contact	MARGARET F CROWE
510(k) history	373 submissions · 325 cleared · 1976-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980632/> 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 14, 2026