

K910968 P.F.C. UNICONDYLAR KNEE SYSTEMAug 26, 1991
173 days to decisionK910968 · Product code: **HRY** · Orthopedic
Source: <https://www.510kdatabase.net/k910968/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Semi-constrained, Cemented, Metal/polymer (HRY)
Date received	Mar 6, 1991
Decision date	Aug 26, 1991
Days to decision	173 days
Third-party review	No

APPLICANT

Company	Johnson & Johnson Orthopaedics, Inc.
Location	Braintree, MA, US
Contact	MARSHA J STONE
510(k) history	22 submissions · 19 cleared · 1990-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k910968/>; 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