

**K012776 DURACON CONSTRAINED POSTERIOR STABILIZED  
(PS) TIBIAL INSERT**Nov 16, 2001  
88 days to decisionK012776 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k012776/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Aug 20, 2001
Decision date	Nov 16, 2001
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Howmedica Osteonics Corp.</b>
Location	Allendale, NJ, US
Contact	MARGARET F CROWE
510(k) history	288 submissions · 288 cleared · 1999-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012776/>, 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 16, 2026