

**K003490 OPUS ROD FIXATION SYSTEM**Dec 8, 2000  
25 days to decisionK003490 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k003490/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Nov 13, 2000
Decision date	Dec 8, 2000
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003490/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026