

**K021164 MACROPORE OS TRAUMA**Jul 1, 2002  
81 days to decisionK021164 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k021164/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 11, 2002
Decision date	Jul 1, 2002
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Macropore Biosurgery, Inc.</b>
Location	San Diego, CA, US
Contact	KENNETH K KLEINHENZ
510(k) history	17 submissions · 16 cleared · 2000-2004

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021164/> 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 20, 2026