

K000992 MACROPOREDX DISTRACTOR SYSTEMJun 26, 2000
90 days to decisionK000992 · Product code: **MQN** · Dental
Source: <https://www.510kdatabase.net/k000992/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Mandibular Fixator And/or Distractor (MQN)
Date received	Mar 28, 2000
Decision date	Jun 26, 2000
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000992/> 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 20, 2026