

K033092 THE GNATHOMETERApr 21, 2004
205 days to decisionK033092 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k033092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Sep 29, 2003
Decision date	Apr 21, 2004
Days to decision	205 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ortho Gnathics, LLC
Location	Pittsburgh, PA, US
Contact	KENNETH J POLK
510(k) history	1 submissions · 1 cleared · 2004-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033092/> 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 July 1, 2026