

**K010118 NORMED MANDIBULAR FIXATION SYSTEM**Aug 14, 2001  
210 days to decisionK010118 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k010118/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Jan 16, 2001
Decision date	Aug 14, 2001
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osteomedics, Inc.</b>
Location	Paramus, NJ, US
Contact	ALBERT ENAYATI
510(k) history	9 submissions · 9 cleared · 2001-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010118/> 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