

**K031989 ORTRAUTЕК ORTHOGNATHIC SYSTEM**Oct 28, 2003  
123 days to decisionK031989 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k031989/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Jun 27, 2003
Decision date	Oct 28, 2003
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tekka</b>
Location	Bethesda, MD, US
Contact	FAYYAZ MEMON
510(k) history	2 submissions · 2 cleared · 2003-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031989/> 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 July 1, 2026