

**K042517 BIOSORB FX AND BIOSORB PDX 1.5 AND 2.0  
SCREWS**Oct 8, 2004  
23 days to decision

K042517 · Product code: JEY · Dental

Source: <https://www.510kdatabase.net/k042517/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Bone (JEY)
Date received	Sep 15, 2004
Decision date	Oct 8, 2004
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Linvatec Biomaterials, Ltd.</b>
Location	Largo, FL, US
Contact	TUIJA ANNALA
510(k) history	5 submissions · 5 cleared · 2003-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042517/>; 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