

K113650 ORTHOFIX SCREWOct 3, 2012
296 days to decisionK113650 · Product code: **OAT** · Dental
Source: <https://www.510kdatabase.net/k113650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Orthodontic (OAT)
Date received	Dec 12, 2011
Decision date	Oct 3, 2012
Days to decision	296 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bonafix Surgical and Dental Implants, LLC
Location	118 W Prive Cr., FL, US
Contact	JUAN TEZAK
510(k) history	2 submissions · 2 cleared · 2012-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113650/> 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 June 13, 2026