

**K120792 TIXOS IMPLANT SYSTEM**Sep 5, 2012  
174 days to decisionK120792 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k120792/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 15, 2012
Decision date	Sep 5, 2012
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Leader Italia S.R.L.</b>
Location	New York, NY, US
Contact	STUART R GOLDMAN
510(k) history	2 submissions · 2 cleared · 2007-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120792/> 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 June 13, 2026