

**K133088 ZX-27**Jan 2, 2015  
459 days to decisionK133088 · Product code: **EJX** · Dental  
Source: <https://www.510kdatabase.net/k133088/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anchor, Preformed (EJX)
Date received	Sep 30, 2013
Decision date	Jan 2, 2015
Days to decision	459 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>M&amp;M Dental Studio, Inc.</b>
Location	New York, NY, US
Contact	IRVING WIESEN
510(k) history	1 submissions · 1 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133088/> 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 5, 2026