

**K132401 MEGA ISQ**Apr 9, 2014  
251 days to decisionK132401 · Product code: **EKX** · Dental  
Source: <https://www.510kdatabase.net/k132401/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Aug 1, 2013
Decision date	Apr 9, 2014
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osstell AB</b>
Location	Alexandria, VA, US
Contact	CHERITA JAMES
510(k) history	4 submissions · 4 cleared · 2008-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132401/> 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 24, 2026