

K142358 Osstell IDxFeb 19, 2015
178 days to decisionK142358 · Product code: **EKX** · Dental
Source: <https://www.510kdatabase.net/k142358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Aug 25, 2014
Decision date	Feb 19, 2015
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osstell AB
Location	Alexandria, VA, US
Contact	KARIN BREDING
510(k) history	4 submissions · 4 cleared · 2008-2019

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