

**K133178 LUXATOR LX HANDPIECE**Nov 24, 2015  
768 days to decisionK133178 · Product code: **EGS** · Dental  
Source: <https://www.510kdatabase.net/k133178/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Contra- And Right-angle Attachment, Dental (EGS)
Date received	Oct 17, 2013
Decision date	Nov 24, 2015
Days to decision	768 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Directa AB</b>
Location	Upplands Vasby, SE
Contact	HENRIC KARSK
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/k133178/> 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 3, 2026