

**K161213 XSmart iQ**Feb 10, 2017  
287 days to decisionK161213 · Product code: **EBW** · Dental  
Source: <https://www.510kdatabase.net/k161213/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Foot, Handpiece And Cord (EBW)
Date received	Apr 29, 2016
Decision date	Feb 10, 2017
Days to decision	287 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dentsply Sirona</b>
Location	York, PA, US
Contact	HELEN LEWIS
Website	<a href="https://www.dentsplysirona.com">https://www.dentsplysirona.com</a>
510(k) history	65 submissions · 65 cleared · 2016-2026

Dentsply Sirona is an American dental equipment manufacturer and consumables producer headquartered in York, US. The company markets products in over 120 countries and operates factories across 21 nations. Dentsply Sirona has received FDA 510(k) clearances from total submissions since 2016. Dental devices represent 78% of the company's regulatory submissions, reflecting its core focus on laboratory equipment, specialty products, and consumables including abutments, CAD/CAM blocks, and restorative materials. The company's latest clearance in 2026 demonstrates continued reg...

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