

**K232063 SaliPen**Dec 13, 2023  
155 days to decisionK232063 · Product code: **QTT** · DentalSource: <https://www.510kdatabase.net/k232063/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over The Counter Electrical Salivary Stimulatory System (QTT)
Date received	Jul 11, 2023
Decision date	Dec 13, 2023
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Saliwell , Ltd.</b>
Location	Harutzim, IL
Contact	Ben Z. Beiski
510(k) history	4 submissions · 4 cleared · 2017-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232063/> 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 May 26, 2026