

K214078 Silk'n ToothwaveJan 13, 2023
382 days to decisionK214078 · Product code: **QMJ** · Dental
Source: <https://www.510kdatabase.net/k214078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Radiofrequency Toothbrush (QMJ)
Date received	Dec 27, 2021
Decision date	Jan 13, 2023
Days to decision	382 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Home Skinovations , Ltd.
Location	Kfar Saba, IL
Contact	Amit Goren
510(k) history	15 submissions · 14 cleared · 2008-2023

REGULATORY CONSULTANT

Consulting firm	A. Stein Regulatory Affairs Consulting , Ltd.
Contact	Amit Goren

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k214078/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026