

K110301 SILK'N FXAug 19, 2011
198 days to decisionK110301 · Product code: **OHS** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k110301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Feb 2, 2011
Decision date	Aug 19, 2011
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110301/> 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 27, 2026