

**K231628 BeShape One™ Device**Sep 29, 2023  
116 days to decisionK231628 · Product code: **OHV** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k231628/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Jun 5, 2023
Decision date	Sep 29, 2023
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beshape Technologies , Ltd.</b>
Location	Kfar-Saba, IL
Contact	Amit Goren
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>A. Stein – Regulatory Affairs Consulting , Ltd.</b>
Contact	Amit Goren

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231628/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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