FDA 510(k) Premarket Notification

K231628 BeShape One™ Device

CLEARED

Sep 29, 2023
116 days to decision

K231628 · Product code: **OHV** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k231628/

SUBMISSION DETAILS

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

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

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