

K231092 T-SHAPE 2Sep 22, 2023
157 days to decisionK231092 · Product code: **NUV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Light Induced Heating (NUV)
Date received	Apr 18, 2023
Decision date	Sep 22, 2023
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	B&M S.R.L. Marketing Nel Benessere
Location	Milano, IT
Contact	Brando Baldan
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Endo Engineering S.R.L.
Contact	Chiara Violini

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/k231092/> 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 26, 2026