

K222748 ShiNeo Silicone ImplantDec 23, 2022
102 days to decisionK222748 · Product code: **MIB** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222748/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone Block (MIB)
Date received	Sep 12, 2022
Decision date	Dec 23, 2022
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shineo Technology Co., Ltd.
Location	New Taipei City, TW
Contact	Wan-Chun Lai
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222748/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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