

K193392 BioSiCar Silicone ImplantJul 20, 2020
227 days to decisionK193392 · Product code: **MIB** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193392/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone Block (MIB)
Date received	Dec 6, 2019
Decision date	Jul 20, 2020
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Metalware Technology Corp.
Location	New Taipei City, TW
Contact	Megan Chang
510(k) history	1 submissions · 1 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193392/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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