

K223051 Pre-Formed Silicone BlockFeb 3, 2023
127 days to decisionK223051 · Product code: **MIB** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k223051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone Block (MIB)
Date received	Sep 29, 2022
Decision date	Feb 3, 2023
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	International Medical Devices, Inc.
Location	Beverly Hills, CA, US
Contact	Dr. James Elist
510(k) history	4 submissions · 4 cleared · 2017-2023

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Lucie Dalet

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

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