

K181387 Pre-Formed Penile Silicone BlockJan 23, 2019
243 days to decisionK181387 · Product code: **MIB** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k181387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone Block (MIB)
Date received	May 25, 2018
Decision date	Jan 23, 2019
Days to decision	243 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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