

K162624 Pre-Formed Penile Silicone BlockFeb 1, 2017
134 days to decisionK162624 · Product code: **MIB** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k162624/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone Block (MIB)
Date received	Sep 20, 2016
Decision date	Feb 1, 2017
Days to decision	134 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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