FDA 510(k) Premarket Notification

K220760 Pre-Formed Penile Silicone Block

CLEARED

May 13, 2022
59 days to decision

K220760 · Product code: **MIB** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220760/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone Block (MIB)
Date received	Mar 15, 2022
Decision date	May 13, 2022
Days to decision	59 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	James Elist
510(k) history	4 submissions · 4 cleared · 2017-2023

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Allison Komiyama

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

CLINICAL EVIDENCE - NCT02477189

Retrospective Analysis of the Safety and Effectiveness of Using the Silicone Block in Penile Surgery

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	400 patients (actual)
Study sites	1 site
Condition studied	Penile Implant
Study type	Observational
Completion date	May 1, 2015
Sponsor	International Medical Devices, Inc. (Industry)

Primary outcome

Number of Adverse Events

Secondary outcome

Self-Esteem Score

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02477189