FDA 510(k) Premarket Notification

K200073 AugMENTA Penile Implant

CLEARED

Sep 30, 2022
990 days to decision

K200073 · Product code: **MIB** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200073/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone Block (MIB)
Date received	Jan 14, 2020
Decision date	Sep 30, 2022
Days to decision	990 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Augmenta, LLC**
Location	Houston, TX, US
Contact	Robert J Cornell
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**DuVal & Associates, P.A.**
Contact	Lisa L. Pritchard

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