FDA 510(k) Premarket Notification

CLEARED

K183163 Intraoperative, Single-Use, Sterile, Silicone Breast Sizer Motiva Implant Matrix

Feb 5, 2019
82 days to decision

K183163 · Product code: **MRD** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k183163/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mammary Sizer (MRD)
Date received	Nov 15, 2018
Decision date	Feb 5, 2019
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Motiva USA, LLC**
Location	New York, NY, US
Contact	ALberto Quesada Rivera
510(k) history	2 submissions · 2 cleared · 2019-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k183163/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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