FDA 510(k) Premarket Notification

K233661 Transorb™ Self-Gripping Resorbable Mesh

CLEARED

Feb 13, 2024
90 days to decision

K233661 · Product code: **OWT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233661/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Abdominal Hernia (OWT)
Date received	Nov 15, 2023
Decision date	Feb 13, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sofradim Production**
Location	Ayer, MA, US
Contact	Mickaël Nicolas
510(k) history	41 submissions · 41 cleared · 1999-2025