FDA 510(k) Premarket Notification

K222919 GORE® ENFORM Biomaterial

CLEARED

Dec 19, 2022
84 days to decision

K222919 · Product code: **OXF** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222919/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Plastic And Reconstructive Surgery (OXF)
Date received	Sep 26, 2022
Decision date	Dec 19, 2022
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**W. L. Gore and Associates, Inc.**
Location	Phoenix, AZ, US
Contact	Barbara L Smith
Website	http://www.gore.com/
510(k) history	3 submissions · 3 cleared · 2018-2022

W. L. Gore and Associates, Inc. is a medical device manufacturer with a manufacturing facility in Phoenix, US. The company specializes in cardiovascular and surgical devices. The company has received FDA 510(k) clearances from total submissions between 2018 and 2022. Its cleared devices focus primarily on cardiovascular applications, including catheter systems and biomaterials for general and plastic surgery. This regulatory record reflects the company's historical activity in the medical device sector. Notable cleared devices include catheter systems designed for cardiov...