FDA 510(k) Premarket Notification

K894478 UHMWPE SURGICAL MESH

CLEARED

Mar 8, 1990
233 days to decision

K894478 · Product code: **KKY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k894478/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Jul 18, 1989
Decision date	Mar 8, 1990
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**Biomet, Inc.**
Location	Mchenry, IL, US
Contact	LONNIE WITHAM
Website	http://www.biomet.com/
510(k) history	441 submissions · 419 cleared · 1978-2026

Biomet, Inc. is an orthopedic medical device manufacturer based in McHenry, US. The company specializes in surgical implants, fixation systems, and trauma solutions. Biomet has maintained a strong FDA 510(k) regulatory record since its first clearance in 1978. The company has received FDA 510(k) clearances from total submissions. Orthopedic devices represent 88% of its submission portfolio, reflecting the company's core focus on joint reconstruction, trauma fixation, and surgical instrumentation. The latest clearance in 2024 demonstrates continued regulatory activity and ...