FDA 510(k) Premarket Notification

K944413 ACM PTFE SURGICAL MESH

CLEARED

Nov 9, 1994
62 days to decision

K944413 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k944413/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Sep 8, 1994
Decision date	Nov 9, 1994
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**American Custom Medical, Inc.**
Location	Lubbock, TX, US
Contact	BRUCE G RUEFER
510(k) history	5 submissions · 5 cleared · 1994-1997