FDA 510(k) Premarket Notification

K003323 COMPOSIX KUGEL MESH, MODEL 0010201,0010202,0010203,0010204,0010205

CLEARED

Jan 22, 2001
90 days to decision

K003323 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k003323/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Oct 24, 2000
Decision date	Jan 22, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Davol, Inc.**
Location	Mchenry, IL, US
Contact	PAULA E BULGER
510(k) history	50 submissions · 47 cleared · 1977-2025