FDA 510(k) Premarket Notification

K973706 DURA-GUARD-DURAL REPAIR PATCH

CLEARED

Dec 24, 1997
86 days to decision

K973706 · Product code: **GXQ** · Neurology
Source: https://www.510kdatabase.net/k973706/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Sep 29, 1997
Decision date	Dec 24, 1997
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Vascular, Inc.**
Location	St. Paul, MN, US
Contact	BARBARA ATZENHOEFER
510(k) history	26 submissions · 25 cleared · 1986-2000