

**K970851 LYOPLANT DURA SUBSTITUTE(VARIOUS)**Dec 9, 1997  
277 days to decisionK970851 · Product code: **GXQ** · Neurology  
Source: <https://www.510kdatabase.net/k970851/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Mar 7, 1997
Decision date	Dec 9, 1997
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Aesculap, Inc.</b>
Location	Burlingame, CA, US
Contact	VICTORIA MACKINNON
510(k) history	207 submissions · 201 cleared · 1991-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970851/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026