

K971507 O2 BOOTNov 7, 1997
196 days to decisionK971507 · Product code: **KPJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k971507/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chamber, Oxygen, Topical, Extremity (KPJ)
Date received	Apr 25, 1997
Decision date	Nov 7, 1997
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gwr Medical, Llp
Location	Chadds Ford, PA, US
Contact	JOSEPH R WESTWOOD
510(k) history	1 submissions · 1 cleared · 1997-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971507/> Data sourced from FDA 510(k) public records (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. - Generated July 4, 2026