

K982870 EPIFILM OTOLOGIC LAMINANov 3, 1998
81 days to decisionK982870 · Product code: **KHJ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k982870/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ)
Date received	Aug 14, 1998
Decision date	Nov 3, 1998
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Xomed, Inc.
Location	Arnold, MO, US
Contact	ROY BERENS
510(k) history	82 submissions · 81 cleared · 1976-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982870/> 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 May 21, 2026