

K122561 ADAPTAIN FASTWRAP, ENVELOCK, GRAFTAINNov 27, 2012
97 days to decisionK122561 · Product code: **KHJ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k122561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ)
Date received	Aug 22, 2012
Decision date	Nov 27, 2012
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ceremed , Inc.
Location	Los Angeles, CA, US
Contact	CHELSEA MITCHELL
510(k) history	20 submissions · 20 cleared · 2004-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122561/> 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 June 2, 2026