

**K132198 ADAPTAIN, ADAPTAIN FASTWRAP, ENVELOCK,
BIOWAI**Sep 12, 2013
58 days to decisionK132198 · Product code: **KHJ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k132198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ)
Date received	Jul 16, 2013
Decision date	Sep 12, 2013
Days to decision	58 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/k132198/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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